

Exhibit 1

ARTICLE

Perineal Powder Use and Risk of Ovarian Cancer

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- Background** Case-control studies have reported an increased risk of ovarian cancer among talc users; however, the only cohort study to date found no association except for an increase in serous invasive ovarian cancers. The purpose of this analysis was to assess perineal powder use and risk of ovarian cancer prospectively in the Women's Health Initiative Observational Study cohort.
- Methods** Perineal powder use was assessed at baseline by self-report regarding application to genitals, sanitary napkins, or diaphragms and duration of use. The primary outcome was self-reported ovarian cancer centrally adjudicated by physicians. Cox proportional hazard regression was used to estimate risk, adjusting for covariates, including person-time until diagnosis of ovarian cancer ($n = 429$), death, loss to follow-up, or September 17, 2012. All statistical tests were two-sided.
- Results** Among 61 576 postmenopausal women, followed for a mean of 12.4 years without a history of cancer or bilateral oophorectomy, 52.6% reported ever using perineal powder. Ever use of perineal powder (hazard ratio [HR]_{adj} = 1.06, 95% confidence interval [CI] = 0.87 to 1.28) was not associated with risk of ovarian cancer compared with never use. Individually, ever use of powder on the genitals (HR_{adj} = 1.12, 95% CI = 0.92 to 1.36), sanitary napkins (HR_{adj} = 0.95, 95% CI = 0.76 to 1.20), or diaphragms (HR_{adj} = 0.92, 95% CI = 0.68 to 1.23) was not associated with risk of ovarian cancer compared with never use, nor were there associations with increasing durations of use. Estimates did not differ when stratified by age or tubal ligation status.
- Conclusion** Based on our results, perineal powder use does not appear to influence ovarian cancer risk.
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In 2013, it is estimated that there will be 22 240 new cases of ovarian cancer and 14 030 ovarian cancer deaths in the United States (US) alone (1). Since the 1960s, there has been speculation that the use of perineal powder is associated with ovarian cancer. In 2006, the International Agency for Research on Cancer (IARC) reviewed studies examining perineal powder use and ovarian cancer and classified talc as a possible carcinogen (2,3). The proportion of US women ever using talc powder on the perineum was estimated in 2001 to be approximately 40% (4), whereas 52% reported ever use of perineal powder in 1993–1998 within the Women's Health Initiative (WHI) (5).

The primary proposed mechanism linking perineal powder use to ovarian cancer is an inflammatory response (6). Talc particulates from perineal application have been shown to migrate to the ovaries (6), disrupting the surface ovarian epithelial tissue leading to entrapment of the talc particles within inclusion cysts (7). Furthermore, tubal ligation and/or hysterectomy, which would eliminate the pathway of talc particulates to the ovaries, are associated with reduced ovarian cancer risk (6).

A meta-analysis examining the risk of ovarian cancer among ever perineal powder users vs non-users showed odds ratios (ORs)

of 1.40 (95% confidence interval [CI] = 1.29 to 1.52) for population-based case-control, 1.12 (95% CI = 0.92 to 1.36) for hospital based case-control, and 1.35 (95% CI = 1.26 to 1.46) for all case-control studies (2). More recently, a large pooled analysis found that ever use of perineal powder increased epithelial ovarian cancer risk by 24% compared with non-use (OR = 1.24, 95% CI = 1.15 to 1.33) (8). Increased risk was associated with invasive serous, endometrioid, clear cell, and borderline serous subtypes of epithelial ovarian cancer (8). However, when looking at the lifetime number of applications of perineal powder, there was no statistically significant trend for increasing applications, attributed to difficulty in recalling details of frequency and duration of perineal powder use (8).

To date there has only been one prospective study conducted examining perineal powder use and risk of ovarian cancer (9). In the Nurses' Health Study (NHS) cohort, no overall association was found between ever use of perineal powder and epithelial ovarian cancer (relative risk [RR] = 1.09, 95% CI = 0.86 to 1.37) or serous ovarian cancers (RR = 1.26, 95% CI = 0.94 to 1.69) (9). However, there was a 40% (95% CI = 1.02 to 1.91) increase in risk for serous

invasive ovarian cancer with ever perineal powder use, which comprises 86% of serous ovarian cancers in this cohort (9).

Limitations of recall bias and misclassification make it difficult to determine the true relationship between perineal powder (10), a commonly used cosmetic product, and ovarian cancer, a disease with poor survival and few known modifiable risk factors. The prior prospective cohort study, which should not be affected by recall bias, had no information on duration of use limiting interpretation. Here we expand on the available evidence by assessing perineal powder use and risk of ovarian cancer in the Women's Health Initiative Observational Study (WHI-OS). The WHI-OS is a large cohort that collected information on several application areas of perineal powder use and their respective durations of use.

Methods

Study Population

The WHI-OS enrolled 93 676 women from 40 clinical centers across the United States from 1993 to 1998 (11). Women were eligible if they were aged 50 to 79 at enrollment, postmenopausal, and planned to reside in the area for at least three years (11). Women were excluded from the WHI-OS if they were participating in another clinical trial, unlikely to survive three years due to medical conditions, or had conditions that would interfere with study participation (11). Participants completed annual mailed questionnaires to update information on risk factors and outcomes, including ovarian cancer (11). Written informed consent was obtained from participants, and all clinical centers were approved by their respective institutional review boards (11). The current analysis was approved by the University of Massachusetts, Amherst Human Subjects Review Committee.

For this analysis, participants were additionally excluded if they reported a bilateral oophorectomy or an unknown number of ovaries at baseline ($n = 20\,960$), a history of any cancer at baseline except nonmelanoma skin cancer ($n = 10\,622$), or were missing exposure or follow up information ($n = 516$). After applying the exclusion criteria, 61 576 participants with 429 adjudicated incident ovarian cancer cases remained.

Exposure Ascertainment

Perineal powder use was assessed via self-report at baseline. Participants were asked, "Have you ever used powder on your private parts (genital areas)?" Those who responded yes further indicated the duration of use with the following possible responses: less than 1 year, 1–4 years, 5–9 years, 10–19 years, or 20 or more years. For persons that reported ever use of a diaphragm, participants were asked, "Did you ever use powder on your diaphragm?" and those who responded yes further indicated duration. The third category evaluated was "Did you ever use powder on a sanitary napkin or pad?" with those responding yes also reporting duration. Each area of application variable was assessed dichotomously and the duration of use, collapsed into fewer categories because of small numbers, was assessed categorically as never, 9 years or less, or 10 or more years. A combined ever perineal powder variable and duration variable for any powder use was created; where ever use was defined as report of ever use of any of the three application categories, never was report of never use for all three categories,

and duration was the maximum duration reported of any single area of application, because we could not exclude the possibility that applications were concurrent. Lastly, all possible combinations of the three application areas were assessed.

Outcome Ascertainment

Ovarian cancer cases were initially self-reported by participants in the WHI-OS on annual questionnaires. Medical records, including hospital discharge summaries and pathology reports, were requested for each self-reported case and adjudicated by a physician at the local Clinical Center and then centrally by the WHI's Clinical Coordinating Center (11).

Covariate Ascertainment

Potential covariates considered included age, race, education, alcohol servings per week, smoking status, metabolic equivalent (MET) hours per week of recreational physical activity, Body Mass Index (BMI), and self-reported family history of ovarian or breast cancer. Reproductive factors considered were age at menarche, age at menopause, age at first birth, age at last birth, parity, breastfeeding duration, history of tubal ligation, history of hysterectomy, history of irregular cycles, history of endometriosis, duration of oral contraceptive use, and duration of postmenopausal hormone use. All covariates were from baseline and were not updated.

Statistical Analysis

To estimate the association between perineal powder use and ovarian cancer, proportional hazard regression models were used. Participants contributed person-time until diagnosis of ovarian cancer, death, loss to follow-up, or September 17, 2012, whichever came first. Participants with other cancers were still considered at risk for ovarian cancer and were not censored at the time of other cancer diagnoses. Information on incident oophorectomy during follow-up was not available and thus participants were not censored in this analysis. The proportional hazards assumption was tested using weighted Schoenfeld residuals.

Covariates were included in the adjusted model according to purposeful selection, where covariates with Wald P values of .25 or less in age-adjusted models were entered into an initial multivariable model and then each covariate was subsequently tested individually via likelihood ratio tests in order of decreasing Wald P values. Variables that had P values of .10 or less during the backwards elimination were kept in the model until a parsimonious model was obtained. Additional variables shown in previous literature (8,9) but not statistically significant in our population were also included in the final multivariable model. Lastly, family history of breast cancer and personal history of endometriosis did not change estimates and were not included in the final multivariable model.

Models fitted included the following independent variables: 1) combined ever perineal powder use, 2) ever powder use by application area (ie, applied to genitals, applied to diaphragm, or applied to sanitary napkins), 3) duration of use by application area, and 4) application area combinations (ie, genital only, diaphragm only, sanitary napkin only, genital and sanitary napkin, genital and diaphragm, diaphragm and sanitary napkin, and all three areas of application). For duration models, test for trend was used to evaluate linear trends across duration categories by modeling the

categories as a continuous variable in the multivariable regression models.

Because powder particles may not reach the ovaries due to tubal ligation and because previous studies have shown a stronger association between powder use and ovarian cancer in women without tubal ligation (4), we separately examined women without tubal ligation. We also stratified by age at baseline, because older women may have had more potential for exposure to talc contaminated with asbestos. Additionally, associations by ovarian cancer histological subtype were evaluated. All analyses were performed using Stata v.12.1 (StataCorp, College Station, TX) and two-sided *P* values of .05 or less were considered statistically significant.

Results

The average age of the participants at baseline was 63.3 years. Participants were followed for a mean of 12.4 years; never powder users were followed for a mean of 12.2 years (range = 0.12 to 17.9 years) and ever powder users were followed for a mean of 12.6 years (range = 0.03 to 18.0). The majority of the participants were white (83.7%), had less than a college degree (56.1%), and were overweight/obese (57.2%). Approximately half (52.6%) of the population reported ever use of perineal powder. Ever powder users were heavier (27.5 kg/m² vs 26.5 kg/m², *P* < .0001) and were more likely to have used oral contraceptives (44% vs 36%, *P* < .0001) and/or diaphragms (50.8% vs 37.3 %, *P* < .0001) than never users (Table 1).

Use of powder on the genitals was associated with a 12% increase in the multivariable-adjusted hazard ratio of ovarian cancer (HR_{adj} = 1.12, 95% CI = 0.92 to 1.36), though this was not statistically significant (Table 2). Use of powder on sanitary napkins (HR_{adj} = 0.95, 95% CI = 0.76 to 1.20) or diaphragms (HR_{adj} = 0.92, 95% CI = 0.68 to 1.23) also was not associated with risk. Duration of powder use on the genitals, sanitary napkins, or on the diaphragm was not associated with ovarian cancer; *P*_{trend} for years of use: .67, .69, and .67 respectively. Combined ever powder use from any of the three application areas did not show an association with ovarian cancer risk (HR_{adj} = 1.06, 95% CI = 0.87 to 1.28). For combined duration of use, which was the longest duration of use among the three areas of application, there was no evidence of an association with risk of ovarian cancer [*P*_{trend} for years of use: .77]. Use of powder on genitals, the most common application area, for 20 or more years was not associated with increased risk of ovarian cancer compared with never users (HR_{adj} = 1.10, 95% CI = 0.82 to 1.48). In a sensitivity analysis, invasive serous ovarian cancer risk was not increased (HR_{adj} = 0.96, 95% CI = 0.65 to 1.41), even in women reporting durations of use greater than 10 years.

There was no evidence of an association between perineal powder use and ovarian cancer risk by category of application (Table 3). Combined ever powder use was not associated with individual subtypes of ovarian cancer (Table 4). The multivariable-adjusted hazard ratio for serous ovarian cancer was 1.16 (95% CI = 0.88 to 1.53). Additionally, duration of combined ever powder use was also not shown to be associated with any subtype of ovarian cancer (results not shown).

The associations of combined ever powder use and ovarian cancer did not statistically differ by tubal ligation status (results not shown). When stratified by age group at baseline, hazard estimates also did not statistically differ (*P*_{interaction} = .37); HR_{adj} for younger than

Table 1. Characteristics of postmenopausal women according to perineal powder use status (n = 61 285): Women’s Health Initiative Observational Study, 1993–2012

Characteristic, n (%)	Never perineal powder use	Ever perineal powder use
	n = 29 066	n = 32 219
Race		
White	24 006 (82.6)	27 336 (84.8)
Nonwhite	4991 (17.2)	4811 (14.9)
Body mass index category, kg/m ²		
<25.0	13 056 (44.9)	12 461 (38.7)
25.0–29.9	9734 (33.5)	10 799 (33.5)
30.0 +	5935 (20.4)	8571 (26.6)
Smoking status		
Never	15 347 (52.8)	15 621 (48.5)
Past	11 481 (39.5)	14 339 (44.5)
Current	1912 (6.6)	1881 (5.8)
Duration of oral contraceptive use, y		
Never	17 877 (61.5)	17 954 (55.7)
<5	6241 (21.5)	7858 (24.4)
5 to <10	2528 (8.7)	3270 (10.2)
10 to <15	1650 (5.7)	2125 (6.6)
15+	760 (2.6)	1005 (3.1)
Diaphragm use	10 826 (37.3)	16 353 (50.8)
Tubal ligation	4929 (17.0)	5901 (18.3)
Hysterectomy	6878 (23.7)	8285 (25.7)
Family history of ovarian cancer	606 (2.1)	660 (2.1)
Parity		
0	3687 (12.7)	3769 (11.7)
1–2	9773 (33.6)	11 585 (36.0)
3–4	11 101 (38.2)	12 609 (39.1)
5+	4365 (15.0)	4098 (12.7)
Age at last birth, y		
Never had term pregnancy	6219 (21.4)	6260 (19.4)
< 20	210 (0.7)	324 (1.0)
20–29	9143 (31.5)	11 480 (35.6)
30+	13 011 (44.8)	13 668 (42.4)
Duration of postmenopausal hormone use, y		
Never	13 381 (46.0)	13 880 (43.1)
<5	6498 (22.4)	7546 (23.4)
5 to <10	3783 (13.0)	4567 (14.2)
10 to <15	2688 (9.3)	3128 (9.7)
15+	2716 (9.3)	3097 (9.6)

50 to 59 years = 1.29, 95% CI = 0.91 to 1.82; HR_{adj} for those 60 to 69 years = 0.94, 95% CI = 0.70 to 1.26; and HR_{adj} for those 70 to 79 years = 1.01, 95% CI = 0.68 to 1.48. When restricted to only whites or to those who had never used oral contraceptives, results were again unchanged.

Discussion

In this large prospective study, ever perineal powder use was not associated with ovarian cancer risk, nor was it associated with ovarian cancer when assessed by area of application, duration of use, or ovarian cancer subtype. While many case-control studies have shown an approximately 24–40% increase in risk of ovarian cancer (2,8) for powder users, we did not find evidence of this association in our large, prospective analysis.

The meta-analysis of 20 case-control studies by Langseth and colleagues found a 35% increase in the odds of epithelial ovarian

Table 2. Age and multivariable-adjusted hazard ratios of ovarian cancer by area of perineal powder application (n = 61576): Women’s Health Initiative Observational Study, 1993–2012

Variable	No. of cases	Person-years	Age-adjusted HR		Multivariable HR*	
			(95% CI)	<i>P</i> _{trend} †	(95% CI)	<i>P</i> _{trend} †
Powder use on genitals						
Never	247	457 855	1.0 (referent)	.63	1.0 (referent)	.67
Ever‡	181	304 867	1.13 (0.93 to 1.37)		1.12 (0.92 to 1.36)	
Less than 9 years	112	173 118	1.24 (0.99 to 1.55)		1.23 (0.98 to 1.54)	
10 or more years	68	129 647	0.98 (0.75 to 1.29)		0.98 (0.75 to 1.29)	
Powder use on sanitary napkins						
Never	336	590 351	1.0 (referent)	.70	1.0 (referent)	.69
Ever‡	93	172 712	0.96 (0.76 to 1.21)		0.95 (0.76 to 1.20)	
Less than 9 years	62	114 305	0.98 (0.75 to 1.28)		0.96 (0.73 to 1.26)	
10 or more years	30	56 174	0.93 (0.64 to 1.35)		0.95 (0.65 to 1.37)	
Powder use on diaphragm						
Never	373	661 239	1.0 (referent)	.78	1.0 (referent)	.67
Ever‡	52	97 714	0.94 (0.70 to 1.25)		0.92 (0.68 to 1.23)	
Less than 9 years	35	67 468	0.93 (0.66 to 1.32)		0.91 (0.64 to 1.30)	
10 or more years	17	29 202	0.99 (0.61 to 1.60)		0.95 (0.58 to 1.56)	
Combined ever powder use§						
Never	197	361 583	1.0 (referent)	.67	1.0 (referent)	.77
Ever‡	232	404 983	1.07 (0.89 to 1.30)		1.06 (0.87 to 1.28)	
Less than 9 years	135	228 931	1.12 (0.90 to 1.39)		1.09 (0.88 to 1.36)	
10 or more years	97	173 307	1.03 (0.81 to 1.31)		1.02 (0.80 to 1.30)	

* Adjusted for: Age (continuous), race (white, nonwhite, missing), oral contraceptive duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), hormone replacement therapy duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), family history (yes, no, missing), age (y) at last birth (never, <20, 20 to <30, 30+, missing), body mass index in kg/m² (<25.0, 25.0 to <30.0, 30.0+, missing), smoking (never, past, current, missing), tubal ligation (yes, no, missing), and parity (0, 1 to 2, 3 to 4, 5+, children, missing).

† Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated in cox proportional hazard regression models; P_{trend} was estimated by modeling categories as continuous. All statistical tests were two-sided.

‡ Person-years may not add up; duration information was missing for some.

§ Combined ever powder use is the longest duration of use among the applications to genitals, sanitary napkins, and diaphragms.

Table 3. Age and multivariable-adjusted hazard ratios for ovarian cancer by combined categories of powder use (n = 61576): Women’s Health Initiative Observational Study, 1993–2012

Variable	No. of cases	Person-years	Age-adjusted HR*	Multivariable HR*
			(95% CI)	(95% CI)
Powder Type Used				
No powder	193	355 523	1.0 (referent)	1.0 (referent)
Only genital powder	96	158 130	1.14 (0.90 to 1.46)	1.13 (0.88 to 1.45)
Only diaphragm powder	19	42 367	0.82 (0.51 to 1.32)	0.80 (0.50 to 1.29)
Only sanitary napkin powder	28	50 051	1.04 (0.70 to 1.54)	1.01 (0.68 to 1.50)
Genital and sanitary napkin powder	55	96 173	1.09 (0.80 to 1.47)	1.08 (0.80 to 1.46)
Genital and diaphragm powder	24	29 858	1.49 (0.98 to 2.28)	1.45 (0.95 to 2.23)
Diaphragm and sanitary napkin powder	4	6 858	1.06 (0.40 to 2.86)	1.02 (0.38 to 2.74)
Genital, diaphragm, and sanitary napkin powder	5	18 331	0.51 (0.21 to 1.24)	0.50 (0.21 to 1.22)

* Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated in cox proportional hazard regression models. All statistical tests were two-sided.

Multivariable HR adjusted for: age (continuous), race (white, nonwhite, missing), oral contraceptive duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), hormone replacement therapy duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), family history (yes, no, missing), age (y) at last birth (never, <20, 20 to <30, 30+, missing), body mass index in kg/m² (<25.0, 25.0 to <30.0, 30.0+, missing), smoking (never, past, current, missing), tubal ligation (yes, no, missing), and parity (0, 1 to 2, 3 to 4, 5+, children missing).

cancer among ever perineal powder users compared to never-users (2), and the pooled analysis of eight case-control studies by Terry and colleagues found a 24% increase in the same group (8). Langseth and colleagues did not assess dose-response or risk among subtypes of ovarian cancer (2). Terry and colleagues assessed lifetime applications of perineal powder and found no statistically significant trend with increasing lifetime applications (8). This corroborates our results that there was no statistically significant risk with increasing duration of perineal powder use, though they were able to capture both frequency and duration (8), whereas we only had duration. Terry and colleagues found elevated risks for invasive serous, borderline serous, endometrioid, and clear cell subtypes of ovarian cancer (8), which we did not observe. One potential reason that case-control studies have found slight increases in risk is the potential for an overestimation of the true association due to recall bias, because the participants are aware of their ovarian cancer status when reporting powder

Table 4. Age and multivariable-adjusted hazard ratios for combined ever powder use by subtype of ovarian cancer (n = 61 576): Women’s Health Initiative Observational Study, 1993–2012

Variable	No. of cases	Person-years	Age-adjusted HR*	Multivariable HR*
			(95% CI)	(95% CI)
Seroust†				
Never	87	355 523	1.0 (referent)	1.0 (referent)
Ever	117	404 983	1.18 (0.89 to 1.56)	1.16 (0.88 to 1.53)
Serous Invasive				
Never	80	355 523	1.0 (referent)	1.0 (referent)
Ever	105	404 983	1.16 (0.87 to 1.55)	1.13 (0.84 to 1.51)
Mucinous				
Never	12	355 523	1.0 (referent)	1.0 (referent)
Ever	13	404 983	0.98 (0.44 to 2.14)	1.03 (0.47 to 2.27)
Endometrioid				
Never	13	355 523	1.0 (referent)	1.0 (referent)
Ever	20	404 983	1.39 (0.69 to 2.79)	1.29 (0.64 to 2.61)
Other				
Never	47	355 523	1.0 (referent)	1.0 (referent)
Ever	54	404 983	1.04 (0.71 to 1.54)	1.04 (0.70 to 1.54)

* Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated in cox proportional hazard regression models. All statistical tests were two-sided. Multivariable HR adjusted for: age (continuous), race (white, nonwhite, missing), oral contraceptive duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), hormone replacement therapy duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), family history (yes, no, missing), age (y) at last birth (never, <20, 20 to <30, 30+, missing), body mass index in kg/m² (<25.0, 25.0 to <30.0, 30.0+, missing), smoking (never, past, current, missing), tubal ligation (yes, no, missing), and parity (0, 1 to 2, 3 to 4, 5+, children missing).

† Includes borderline cancers.

exposure. The prospective nature of our study would eliminate the potential for recall bias. Additionally, the case-control studies tended to have a younger population than our study, which included both premenopausal and postmenopausal ovarian cancers (2,8), whereas the WHI cohort consisted only of postmenopausal ovarian cancers. Ovarian cancer that occurs prior to menopause may have a different etiology than ovarian cancer occurring afterwards.

We found similar results to that of the NHS, the only other prospective cohort, which had a similar sample size and number of ovarian cancer cases to our study. Ever use of perineal powder did not appear to be associated with ovarian cancer in the NHS (9), similar to our findings. The results of Gertig and colleagues were also null for use on the genitals and for use on sanitary napkins (9). Additionally, neither our study nor the NHS found associations with serous ovarian cancer, endometrioid, or mucinous ovarian cancers, although subgroup sample size may have reduced statistical power to test these associations. In contrast to our results, the study by Gertig and colleagues found a 40% increase in invasive serous ovarian cancer among ever powder users compared with never powder users (9).

Strengths of our study included large sample size with a substantial number of ovarian cancer cases, a prospective cohort design, good case ascertainment, and detailed information on most ovarian cancer risk factors. We also had information on duration of powder use, qualifiers not available in several earlier studies, including the previous cohort study (2,8,9).

One potential limitation of our analyses includes a lack of information regarding oophorectomy after baseline, which would result in the inclusion of some women not at risk for ovarian cancer in the analytical cohort. However, the impact was likely to be minor, as a previous study in the WHI-OS had reported the number of persons with incident bilateral oophorectomies to be less than 250 (out of more than 90 000 participants) during nearly eight years of follow-up (12). While the prospective nature of the study design

eliminates recall bias, it does not eliminate potential for nondifferential misclassification of the exposure. Women still needed to recall past perineal powder use and duration and thus may have trouble recollecting specifics regarding the use of perineal powder, leading to a bias toward the null. Information regarding powder use was not collected after baseline, and there is potential for never users to begin using powder; however, this is unlikely because the women are postmenopausal, reducing need to use perineal powder on diaphragms or sanitary napkins. We also had no specific data regarding the frequency of powder use in our sample. Frequency of use, as well as duration may influence ovarian cancer risk. We may have been comparing long-term infrequent users with short-term frequent users. If we had frequency of use in addition to the duration, we could have looked at intensity of use, which may be more accurate, and shown a dose response relationship. However, Terry and colleagues did not find a dose response relationship either when taking into account frequency and duration (8).

When restricted to women without tubal ligation status, the estimates for the association between combined ever perineal powder use and ovarian cancer were not increased. While some studies have found stronger associations between powder use and ovarian cancer in women that have not undergone a tubal ligation (4), the results from our study did not support this previous finding. The pooled analysis (8) and the NHS cohort (9) also did not find evidence of stronger associations in women without tubal ligations.

While we had information on duration of use, it is unknown during which years the perineal powder was used. Talc powder had potential for asbestos contamination (13) until 1976, when the Cosmetic, Toiletry, and Fragrance Association required all cosmetic talc products to be free of asbestos (14). Therefore, those using powder prior to 1976 may have been potentially exposed to asbestos, a known carcinogen. The pooled analysis and meta-analysis also included case-control studies not within the United States

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(2,8), which potentially have different regulations regarding perineal powder and earlier studies that may have been more likely to include exposure to contaminated perineal powder (2). However, risk estimates in more recent studies are similar to earlier studies (2), reducing the likelihood that confounding by asbestos is driving the findings. Additionally, assuming older women in the cohort could have been exposed longer to perineal powder with potential contamination compared with younger women, we did not see statistically significant differences in risk when stratified by age group, further suggesting asbestos contamination is not a likely explanation.

The WHI-OS queried general perineal powder use rather than talc powder use, and we had no specific information regarding the content of talc in products used, which the previous literature reviewed by IARC suggested to be the possible carcinogen of concern (2). However, the NHS cohort and most studies included within the pooled analyses asked about general perineal powder use as well (2,8,9). In summary, perineal powder use did not appear to be associated with ovarian cancer risk in this large sample of postmenopausal women, even with use for long durations.

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Exhibit 2

Meeting January 14 1965

The Environment and Disease: Association or Causation?

by Sir Austin Bradford Hill CBE DSC FRCP(hon) FRS
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Amongst the objects of this newly-founded Section of Occupational Medicine are firstly 'to provide a means, not readily afforded elsewhere, whereby physicians and surgeons with a special knowledge of the relationship between sickness and injury and conditions of work may discuss their problems, not only with each other, but also with colleagues in other fields, by holding joint meetings with other Sections of the Society'; and, secondly, 'to make available information about the physical, chemical and psychological hazards of occupation, and in particular about those that are rare or not easily recognized'.

At this first meeting of the Section and before, with however laudable intentions, we set about instructing our colleagues in other fields, it will be proper to consider a problem fundamental to our own. How in the first place do we detect these relationships between sickness, injury and conditions of work? How do we determine what are physical, chemical and psychological hazards of occupation, and in particular those that are rare and not easily recognized?

There are, of course, instances in which we can reasonably answer these questions from the general body of medical knowledge. A particular, and perhaps extreme, physical environment cannot fail to be harmful; a particular chemical is known to be toxic to man and therefore suspect on the factory floor. Sometimes, alternatively, we may be able to consider what *might* a particular environment do to man, and then see whether such consequences are indeed to be found. But more often than not we have no such guidance, no such means of proceeding; more often than not we are dependent upon our observation and enumeration of defined events for which we then seek antecedents. In other words we see that the event B is associated with the environmental feature A, that, to take a specific example, some form of respiratory illness is associated with a dust in the environment. In what circumstances can we pass from this

President's Address

observed *association* to a verdict of *causation*? Upon what basis should we proceed to do so?

I have no wish, nor the skill, to embark upon a philosophical discussion of the meaning of 'causation'. The 'cause' of illness may be immediate and direct, it may be remote and indirect underlying the observed association. But with the aims of occupational, and almost synonymously preventive, medicine in mind the decisive question is whether the frequency of the undesirable event B will be influenced by a change in the environmental feature A. *How* such a change exerts that influence may call for a great deal of research. However, before deducing 'causation' and taking action we shall not invariably have to sit around awaiting the results of that research. The whole chain may have to be unravelled or a few links may suffice. It will depend upon circumstances.

Disregarding then any such problem in semantics we have this situation. Our observations reveal an association between two variables, perfectly clear-cut and beyond what we would care to attribute to the play of chance. What aspects of that association should we especially consider before deciding that the most likely interpretation of it is causation?

(1) *Strength*. First upon my list I would put the strength of the association. To take a very old example, by comparing the occupations of patients with scrotal cancer with the occupations of patients presenting with other diseases, Percival Pott could reach a correct conclusion because of the *enormous* increase of scrotal cancer in the chimney sweeps. 'Even as late as the second decade of the twentieth century', writes Richard Doll (1964), 'the mortality of chimney sweeps from scrotal cancer was some 200 times that of workers who were not specially exposed to tar or mineral oils and in the eighteenth century the relative difference is likely to have been much greater.'

To take a more modern and more general example upon which I have now reflected for over fifteen years, prospective inquiries into smoking have shown that the death rate from cancer of the lung in cigarette smokers is nine to ten times the rate in non-smokers and the rate in heavy cigarette smokers is twenty to thirty times

as great. On the other hand the death rate from coronary thrombosis in smokers is no more than twice, possibly less, the death rate in non-smokers. Though there is good evidence to support causation it is surely much easier in this case to think of some features of life that may go hand-in-hand with smoking – features that might conceivably be the real underlying cause or, at the least, an important contributor, whether it be lack of exercise, nature of diet or other factors. But to explain the pronounced excess in cancer of the lung in any other environmental terms requires some feature of life so intimately linked with cigarette smoking and with the amount of smoking that such a feature should be easily detectable. If we cannot detect it or reasonably infer a specific one, then in such circumstances I think we are reasonably entitled to reject the vague contention of the armchair critic ‘you can’t prove it, there *may* be such a feature’.

Certainly in this situation I would reject the argument sometimes advanced that what matters is the absolute difference between the death rates of our various groups and not the ratio of one to other. That depends upon what we want to know. If we want to know how many extra deaths from cancer of the lung will take place through smoking (i.e. presuming causation), then obviously we must use the absolute differences between the death rates – 0.07 per 1,000 per year in non-smoking doctors, 0.57 in those smoking 1–14 cigarettes daily, 1.39 for 15–24 cigarettes daily and 2.27 for 25 or more daily. But it does not follow here, or in more specifically occupational problems, that this best measure of the effect upon mortality is also the best measure in relation to aetiology. In this respect the ratios of 8, 20 and 32 to 1 are far more informative. It does not, of course, follow that the differences revealed by ratios are of any practical importance. Maybe they are, maybe they are not; but that is another point altogether.

We may recall John Snow’s classic analysis of the opening weeks of the cholera epidemic of 1854 (Snow 1855). The death rate that he recorded in the customers supplied with the grossly polluted water of the Southwark and Vauxhall Company was in truth quite low – 71 deaths in each 10,000 houses. What stands out vividly is the fact that the small rate is 14 times the figure of 5 deaths per 10,000 houses supplied with the sewage-free water of the rival Lambeth Company.

In thus putting emphasis upon the strength of an association we must, nevertheless, look at the obverse of the coin. We must not be too ready to dismiss a cause-and-effect hypothesis merely on

the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so. Relatively few persons harbouring the meningococcus fall sick of meningococcal meningitis. Relatively few persons occupationally exposed to rat’s urine contract Weil’s disease.

(2) *Consistency*: Next on my list of features to be specially considered I would place the *consistency* of the observed association. Has it been repeatedly observed by different persons, in different places, circumstances and times?

This requirement may be of special importance for those rare hazards singled out in the Section’s terms of reference. With many alert minds at work in industry today many an environmental association may be thrown up. Some of them on the customary tests of statistical significance will appear to be unlikely to be due to chance. Nevertheless whether chance is the explanation or whether a true hazard has been revealed may sometimes be answered only by a repetition of the circumstances and the observations.

Returning to my more general example, the Advisory Committee to the Surgeon-General of the United States Public Health Service found the association of smoking with cancer of the lung in 29 retrospective and 7 prospective inquiries (US Department of Health, Education & Welfare 1964). The lesson here is that broadly the same answer has been reached in quite a wide variety of situations and techniques. In other words we can justifiably infer that the association is not due to some constant error or fallacy that permeates every inquiry. And we have indeed to be on our guard against that.

Take, for instance, an example given by Heady (1958). Patients admitted to hospital for operation for peptic ulcer are questioned about recent domestic anxieties or crises that may have precipitated the acute illness. As controls, patients admitted for operation for a simple hernia are similarly quizzed. But, as Heady points out, the two groups may not be *in pari materia*. If your wife ran off with the lodger last week you still have to take your perforated ulcer to hospital without delay. But with a hernia you might prefer to stay at home for a while – to mourn (or celebrate) the event. No number of exact repetitions would remove or necessarily reveal that fallacy.

We have, therefore, the somewhat paradoxical position that the different results of a different inquiry certainly cannot be held to refute the

original evidence; yet the same results from precisely the same form of inquiry will not invariably greatly strengthen the original evidence. I would myself put a good deal of weight upon similar results reached in quite different ways, e.g. prospectively and retrospectively.

Once again looking at the obverse of the coin there will be occasions when repetition is absent or impossible and yet we should not hesitate to draw conclusions. The experience of the nickel refiners of South Wales is an outstanding example. I quote from the Alfred Watson Memorial Lecture that I gave in 1962 to the Institute of Actuaries:

'The population at risk, workers and pensioners, numbered about one thousand. During the ten years 1929 to 1938, sixteen of them had died from cancer of the lung, eleven of them had died from cancer of the nasal sinuses. At the age specific death rates of England and Wales at that time, one might have anticipated one death from cancer of the lung (to compare with the 16), and a fraction of a death from cancer of the nose (to compare with the 11). In all other bodily sites cancer had appeared on the death certificate 11 times and one would have expected it to do so 10-11 times. There had been 67 deaths from all other causes of mortality and over the ten years' period 72 would have been expected at the national death rates. Finally division of the population at risk in relation to their jobs showed that the excess of cancer of the lung and nose had fallen wholly upon the workers employed in the chemical processes.

'More recently my colleague, Dr Richard Doll, has brought this story a stage further. In the nine years 1948 to 1956 there had been, he found, 48 deaths from cancer of the lung and 13 deaths from cancer of the nose. He assessed the numbers expected at normal rates of mortality as, respectively 10 and 0.1.

'In 1923, long before any special hazard had been recognized, certain changes in the refinery took place. No case of cancer of the nose has been observed in any man who first entered the works after that year, and in these men there has been no excess of cancer of the lung. In other words, the excess in both sites is uniquely a feature in men who entered the refinery in, roughly, the first 23 years of the present century.

'No causal agent of these neoplasms has been identified. Until recently no animal experimentation had given any clue or any support to this wholly statistical evidence. Yet I wonder if any of us would hesitate to accept it as proof of a grave industrial hazard?' (Hill 1962).

In relation to my present discussion I know of no parallel investigation. We have (or certainly had) to make up our minds on a unique event; and there is no difficulty in doing so.

(3) *Specificity*: One reason, needless to say, is the specificity of the association, the third characteristic which invariably we must consider. If, as here, the association is limited to specific workers and to particular sites and types of disease and there is no association between the work and other modes of dying, then clearly that is a strong argument in favour of causation.

We must not, however, over-emphasize the importance of the characteristic. Even in my present example there is a cause and effect relationship with two different sites of cancer – the lung and the nose. Milk as a carrier of infection and, in that sense, the cause of disease can produce such a disparate galaxy as scarlet fever, diphtheria, tuberculosis, undulant fever, sore throat, dysentery and typhoid fever. Before the discovery of the underlying factor, the bacterial origin of disease, harm would have been done by pushing too firmly the need for specificity as a necessary feature before convicting the dairy.

Coming to modern times the prospective investigations of smoking and cancer of the lung have been criticized for not showing specificity – in other words the death rate of smokers is higher than the death rate of non-smokers from many causes of death (though in fact the results of Doll & Hill, 1964, do not show that). But here surely one must return to my first characteristic, the strength of the association. If other causes of death are raised 10, 20 or even 50% in smokers whereas cancer of the lung is raised 900-1,000% we have specificity – a specificity in the magnitude of the association.

We must also keep in mind that diseases may have more than one cause. It has always been possible to acquire a cancer of the scrotum without sweeping chimneys or taking to mule-spinning in Lancashire. One-to-one relationships are not frequent. Indeed I believe that multi-causation is generally more likely than single causation though possibly if we knew all the answers we might get back to a single factor.

In short, if specificity exists we may be able to draw conclusions without hesitation; if it is not apparent, we are not thereby necessarily left sitting irresolutely on the fence.

(4) *Temporality*: My fourth characteristic is the temporal relationship of the association – which is the cart and which the horse? This is a question which might be particularly relevant with diseases of slow development. Does a particular diet lead to disease or do the early stages of the disease lead to those peculiar dietetic habits? Does a

particular occupation or occupational environment promote infection by the tubercle bacillus or are the men and women who select that kind of work more liable to contract tuberculosis whatever the environment – or, indeed, have they already contracted it? This temporal problem may not arise often but it certainly needs to be remembered, particularly with selective factors at work in industry.

(5) *Biological gradient*: Fifthly, if the association is one which can reveal a biological gradient, or dose-response curve, then we should look most carefully for such evidence. For instance, the fact that the death rate from cancer of the lung rises linearly with the number of cigarettes smoked daily, adds a very great deal to the simpler evidence that cigarette smokers have a higher death rate than non-smokers. That comparison would be weakened, though not necessarily destroyed, if it depended upon, say, a much heavier death rate in light smokers and a lower rate in heavier smokers. We should then need to envisage some much more complex relationship to satisfy the cause-and-effect hypothesis. The clear dose-response curve admits of a simple explanation and obviously puts the case in a clearer light.

The same would clearly be true of an alleged dust hazard in industry. The dustier the environment the greater the incidence of disease we would expect to see. Often the difficulty is to secure some satisfactory quantitative measure of the environment which will permit us to explore this dose-response. But we should invariably seek it.

(6) *Plausibility*: It will be helpful if the causation we suspect is biologically plausible. But this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day.

To quote again from my Alfred Watson Memorial Lecture (Hill 1962), there was

‘... no biological knowledge to support (or to refute) Pott’s observation in the 18th century of the excess of cancer in chimney sweeps. It was lack of biological knowledge in the 19th that led a prize essayist writing on the value and the fallacy of statistics to conclude, amongst other “absurd” associations, that “it could be no more ridiculous for the stranger who passed the night in the steerage of an emigrant ship to ascribe the typhus, which he there contracted, to the vermin with which bodies of the sick might be infected”. And coming to nearer times, in the 20th century there was no biological knowledge to support the evidence against rubella.’

In short, the association we observe may be one new to science or medicine and we must not dismiss it too light-heartedly as just too odd. As Sherlock Holmes advised Dr Watson, ‘when you have eliminated the impossible, whatever remains, however improbable, must be the truth.’

(7) *Coherence*: On the other hand the cause-and-effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease – in the expression of the Advisory Committee to the Surgeon-General it should have coherence.

Thus in the discussion of lung cancer the Committee finds its association with cigarette smoking coherent with the temporal rise that has taken place in the two variables over the last generation and with the sex difference in mortality – features that might well apply in an occupational problem. The known urban/rural ratio of lung cancer mortality does not detract from coherence, nor the restriction of the effect to the lung.

Personally, I regard as greatly contributing to coherence the histopathological evidence from the bronchial epithelium of smokers and the isolation from cigarette smoke of factors carcinogenic for the skin of laboratory animals. Nevertheless, while such laboratory evidence can enormously strengthen the hypothesis and, indeed, may determine the actual causative agent, the lack of such evidence cannot nullify the epidemiological observations in man. Arsenic can undoubtedly cause cancer of the skin in man but it has never been possible to demonstrate such an effect on any other animal. In a wider field John Snow’s epidemiological observations on the conveyance of cholera by the water from the Broad Street pump would have been put almost beyond dispute if Robert Koch had been then around to isolate the vibrio from the baby’s nappies, the well itself and the gentleman in delicate health from Brighton. Yet the fact that Koch’s work was to be awaited another thirty years did not really weaken the epidemiological case though it made it more difficult to establish against the criticisms of the day – both just and unjust.

(8) *Experiment*: Occasionally it is possible to appeal to experimental, or semi-experimental, evidence. For example, because of an observed association some preventive action is taken. Does it in fact prevent? The dust in the workshop is reduced, lubricating oils are changed, persons stop smoking cigarettes. Is the frequency of the associated events affected? Here the strongest

support for the causation hypothesis may be revealed.

(9) *Analogy*: In some circumstances it would be fair to judge by analogy. With the effects of thalidomide and rubella before us we would surely be ready to accept slighter but similar evidence with another drug or another viral disease in pregnancy.

Here then are nine different viewpoints from all of which we should study association before we cry causation. What I do not believe – and this has been suggested – is that we can usefully lay down some hard-and-fast rules of evidence that *must* be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question – is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?

Tests of Significance

No formal tests of significance can answer those questions. Such tests can, and should, remind us of the effects that the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that they contribute nothing to the 'proof' of our hypothesis.

Nearly forty years ago, amongst the studies of occupational health that I made for the Industrial Health Research Board of the Medical Research Council was one that concerned the workers in the cotton-spinning mills of Lancashire (Hill 1930). The question that I had to answer, by the use of the National Health Insurance records of that time, was this: Do the workers in the cardroom of the spinning mill, who tend the machines that clean the raw cotton, have a sickness experience in any way different from that of other operatives in the same mills who are relatively unexposed to the dust and fibre that were features of the cardroom? The answer was an unqualified 'Yes'. From age 30 to age 60 the cardroom workers suffered over three times as much from respiratory causes of illness whereas from non-respiratory causes their experience was not different from that of the other workers. This pronounced difference with the respiratory causes was derived not from abnormally long periods of sickness but rather from an excessive number of repeated absences from work of the cardroom workers.

All this has rightly passed into the limbo of forgotten things. What interests me today is this: My results were set out for men and women separately and for half a dozen age groups in 36 tables. So there were plenty of sums. Yet I cannot find that anywhere I thought it necessary to use a test of significance. The evidence was so clear-cut, the differences between the groups were mainly so large, the contrast between respiratory and non-respiratory causes of illness so specific, that no formal tests could really contribute anything of value to the argument. So why use them?

Would we think or act that way today? I rather doubt it. Between the two worlds there was a strong case for emphasizing to the clinician and other research workers the importance of not overlooking the effects of the play of chance upon their data. Perhaps too often generalities were based upon two men and a laboratory dog while the treatment of choice was deduced from a difference between two bedfuls of patients and might easily have no true meaning. It was therefore a useful corrective for statisticians to stress, and to teach the need for, tests of significance merely to serve as guides to caution before drawing a conclusion, before inflating the particular to the general.

I wonder whether the pendulum has not swung too far – not only with the attentive pupils but even with the statisticians themselves. To decline to draw conclusions without standard errors can surely be just as silly? Fortunately I believe we have not yet gone so far as our friends in the USA where, I am told, some editors of journals will return an article because tests of significance have not been applied. Yet there are innumerable situations in which they are totally unnecessary – because the difference is grotesquely obvious, because it is negligible, or because, whether it be formally significant or not, it is too small to be of any practical importance. What is worse the glitter of the *t* table diverts attention from the inadequacies of the fare. Only a tithe, and an unknown tithe, of the factory personnel volunteer for some procedure or interview, 20% of patients treated in some particular way are lost to sight, 30% of a randomly-drawn sample are never contacted. The sample may, indeed, be akin to that of the man who, according to Swift, 'had a mind to sell his house and carried a piece of brick in his pocket, which he showed as a pattern to encourage purchasers'. The writer, the editor and the reader are unmoved. The magic formulæ are there.

Of course I exaggerate. Yet too often I suspect we waste a deal of time, we grasp the shadow and

lose the substance, we weaken our capacity to interpret data and to take reasonable decisions whatever the value of P . And far too often we deduce 'no difference' from 'no significant difference'. Like fire, the χ^2 test is an excellent servant and a bad master.

The Case for Action

Finally, in passing from association to causation I believe in 'real life' we shall have to consider what flows from that decision. On scientific grounds we should do no such thing. The evidence is there to be judged on its merits and the judgment (in that sense) should be utterly independent of what hangs upon it – or who hangs because of it. But in another and more practical sense we may surely ask what is involved in our decision. In occupational medicine our object is usually to take action. If this be operative cause and that be deleterious effect, then we shall wish to intervene to abolish or reduce death or disease.

While that is a commendable ambition it almost inevitably leads us to introduce differential standards before we convict. Thus on relatively slight evidence we might decide to restrict the use of a drug for early-morning sickness in pregnant women. If we are wrong in deducing causation from association no great harm will be done. The good lady and the pharmaceutical industry will doubtless survive.

On fair evidence we might take action on what appears to be an occupational hazard, e.g. we might change from a probably carcinogenic oil

to a non-carcinogenic oil in a limited environment and without too much injustice if we are wrong. But we should need very strong evidence before we made people burn a fuel in their homes that they do not like or stop smoking the cigarettes and eating the fats and sugar that they do like. In asking for very strong evidence I would, however, repeat emphatically that this does not imply crossing every 't', and swords with every critic, before we act.

All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.

Who knows, asked Robert Browning, but the world may end tonight? True, but on available evidence most of us make ready to commute on the 8.30 next day.

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Exhibit 3



The evolution of evidence hierarchies: what can Bradford Hill's 'guidelines for causation' contribute?

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'A main cause of philosophical disease – a one-sided diet: one nourishes one's thinking with only one kind of example.' Ludwig Wittgenstein

Introduction: when non-RCT evidence is sufficient to conclude that the intervention caused the outcome

High quality randomized controlled trials (RCTs) (concealed allocation, relevant groups blinded and sufficiently powered, etc.) will usually provide sufficient evidence to establish that a particular treatment caused an outcome. Yet sufficiently well-conducted RCTs are rare.¹ Trials can be under-powered,² or unsuccessfully blinded,^{3,4} and often suffer from many undetected biases. The results of most RCTs are therefore often insufficient to establish causation. At the same time, RCTs are often not required to establish causation.⁵ Treatments including the Heimlich manoeuvre, cardiac defibrillation and parachutes to prevent death⁶ have never been tested in RCTs, yet their effectiveness is surely strongly supported by evidence.

Evidence-grading systems that place randomized trials at the top of a hierarchy^{7–13} will deliver misleading conclusions in cases where RCTs are insufficient or unnecessary. According to these hierarchies, trails of homeopathy – often generating positive results and generally of higher quality than RCTs of conventional treatments¹⁴ – will be considered to provide strong evidence, whereas the evidence base for the Heimlich manoeuvre to unblock airways and parachutes to prevent death will be judged as less strongly supported by evidence.

Sir Austin Bradford Hill, in a widely-cited 'pre-EBM' system for appraising evidence, suggested that several relevant factors must be considered

before concluding causation. We investigated and revised the Bradford Hill 'guidelines for causation', in order to refine our intuitions about whether to believe that intervention is effective. Our intention is not to debunk previous attempts to grade evidence, but rather to contribute to their natural evolution and development.

Revising Bradford Hill's guidelines

We believe that Bradford Hill's guidelines form a useful tool as they stand. Nevertheless, they can be modified in ways that make them easier to use. For instance, some of the guidelines, such as 'specificity' can safely be omitted while others, such as 'experiment' and 'strength' can be combined; still others, such as 'biological plausibility' can benefit from a more detailed analysis. Moreover, the guidelines have an inherent structure that is unclear in the original exposition. We propose that the guidelines be organized into the following three categories:

- (1) *Direct evidence* from studies (randomized or non-randomized) that a probabilistic association between intervention and outcome is causal and not spurious;
- (2) *Mechanistic evidence* for the alleged causal process that connects the intervention and the outcome;
- (3) *Parallel evidence* that supports the causal hypothesis suggested in a study, with related studies that have similar results.

A previous attempt to impose a structure on the guidelines¹⁵ may have oversimplified, claiming, for example, that 'analogy' (our 'similarity') is a 'mechanistic' consideration (which, as shall become clear below, is a category error).

guideline. He was also responsible for the suggestion to combine and omit some of the guidelines

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We use the term 'guidelines' over the more common 'criteria'^{16–21} because Bradford Hill did not regard any of the guidelines as necessary or sufficient for establishing causation¹¹: '... none of these viewpoints can bring indisputable evidence for or against a cause-and-effect hypothesis and equally none can be required as a *sine qua non*'.²² To cite his example, 'It will be helpful if the causation we suspect is *biologically plausible*, though this is a feature we cannot demand. What is biologically plausible depends on the biological knowledge of the day.'²² Bradford Hill gave similar warnings about all the other guidelines (except, as we shall see, 'temporality'). Rather than 'criteria', they are best viewed as factors to be considered when assessing whether there is evidence for causation, or 'guidelines' for short.

Aware of detailed descriptions of the original guidelines,^{15,23,24} we shall limit ourselves to describing our re-structured and revised version (Table 1). We shall then apply the Revised Bradford Hill Guidelines to real examples of likely causation despite lack of support from RCTs.

Direct evidence

The first three of the revised guidelines help assess whether 'direct' evidence of a probabilistic associ-

ation between two factors is causal rather than spurious.

Size of effect not attributable to plausible confounding

Plausible confounders are factors which are not directly related to the experimental intervention, are unequally distributed between treatment and control groups, and are likely to determine the outcome. For instance, we might observe that depressed people who exercise recover more quickly. Is the association between exercise and more expedient recovery from depressive symptoms causal? We cannot answer this question without ruling out potential confounders. Those who take regular exercise might also (on average) get more sun, eat healthier foods or they might simply believe more strongly that their depression will go away. These other factors, rather than exercise, might cause their speedier recovery.

Different ailments and studies are at risk from different confounders, so the judgement of whether *plausible* confounders have been ruled out will depend on careful examination of each case. For ailments that are responsive to expectations (such as depression and pain) the confounding effects of expectations will have to be ruled out, which can be achieved by blinding the patients and caregivers. When the assessment of outcomes is prone to influence from observer bias (such as blood pressure), potential confounding by variable measurements has to be ruled out, perhaps by standardizing the measurement procedure and by blinding the investigators in charge of collecting the data and evaluating the outcomes.

Yet sometimes the *strength* of the association (the size of the effect) will be greater than the combined effect of plausible confounders. In these cases, although plausible confounders have not been ruled by the design of the study, the large observed effect has swamped the combined effects of any plausible confounders. For example, the observed effects of general anaesthesia are unlikely to be accountable by selection bias, placebo effects or reporting bias. Thus, the failure to test the effects of general anaesthetics in double-blind, placebo controlled trials should not count against our beliefs that they cause reversible loss of consciousness.

Table 1
Bradford Hill's original guidelines and proposed revisions

Type of evidence	Revised, structured guidelines	Hill's original guidelines
Direct	Size of effect not attributable to plausible confounding	Experiment
	Appropriate temporal and/or spatial proximity (cause precedes effect and effect occurs after a plausible interval; cause occurs at the same site as the intervention)	Strength
	Dose-responsiveness and reversibility	Temporality
Mechanistic	Evidence for a mechanism of action (biological, chemical, mechanical)	Biological gradient Biological plausibility
Parallel	Coherence	Coherence
	Replicability	Consistency
	Similarity	Analogy

Since one should compare the strength of association (size of effect) with the potential degree of bias, we have combined these into a single comparative guideline to emphasize this intrinsic comparison: *is plausible confounding less than the size of effect?*

A note of caution about strong *relative* effects (but small absolute effects) must be issued. Although 'weak' causes may be as real as 'strong' causes, it takes fewer (or 'weaker') confounders to account for a small absolute effect than for a large absolute effect. We therefore must be more careful when inferring from a strong relative (but small absolute) effect that an association is causal. At the same time, in many cases strong relative effects can provide strong support for the causal hypothesis. For instance, although the increased risk for lung cancer in smokers Bradford Hill cited was extremely low (0.07 per 1000 for non-smokers, 0.57 for smokers), the death rate for lung cancer in cigarette smokers was over 9 times the rate for non-smokers and thus provided good evidence for causation.²²

Our omission of the 'experiment' guideline should not be interpreted as a sign that any observational study will do. Observational studies must demonstrate larger effects than randomized trials since they are at risk from selection bias (because the allocation to treatment groups is neither randomized nor concealed) and performance bias (because the participants and caregivers are not blinded). Whether the effect size in a particular observational study is sufficiently large to rule out the combined effects of selection and performance bias will vary from case to case. If investigators conducting an observational study have been vigilant in attempts to reduce selection bias (through careful selection of the control groups and *post hoc* adjustments), and the outcome is objective, the observational study might not have to demonstrate a dramatic effect in order to support causation.²⁵⁻²⁷ In most other cases, however, the effect in an observational study will have to be dramatic in order to be confident that plausible confounders have been ruled out.⁵

In fact, our guideline can be more stringent than current EBM standards of evidence. According to hierarchies of evidence, RCTs with a low risk of bias often provide sufficient evidence to support causation. We require that, in addition to being at low risk, the effect size outweighs the combined

effects of any residual bias. For example, although most systematic reviews of high quality RCTs of SSRIs suggest that these drugs enjoy a statistically significant benefit over 'placebo',^{28,29} the absolute benefit is modest – a recent study suggests it is 6% (2–9%).³⁰ Yet one often overlooked source of confounding in these studies is the identifiable side-effects of the drug. If patients identify the drugs because of the side-effects (and independently of their effects on depression), then their expectations regarding recovery might be higher than if they knew they were taking a 'mere' placebo. To rule out the possible confounding effect of expectations, 'active placebos', which imitate the side-effects of SSRIs need to be employed. A systematic review of antidepressants versus 'active' placebos found that the drug less placebo difference was substantially reduced.³¹ Besides confounding expectations, systematic reviews of SSRIs (like most systematic reviews) are likely to be confounded to some degree by publication bias,^{32,33} funding source bias³⁴ and data mining in the original studies.³⁵ A careful calculation of the combined effects of these plausible confounders must be made before claiming that the systematic reviews of SSRIs support the claim that the drugs cause the reduction in depressive symptoms. Such calculations have not (to our knowledge) been made, so this guideline, unlike current hierarchies, does not necessarily support the existence of (non-placebo) effects of SSRIs.

Appropriate temporal and spatial proximity (encompassing and extending Bradford Hill's 'Temporality')

'Does a particular diet lead to disease or do the early stages of the disease lead to particular dietetic habits?'²² The temporal part of this guideline is necessary: causes precede their effects and is therefore a true criterion. However, we should also ask: is the time *interval* between cause and effect consistent with the supposed mechanism? In general, the shorter the temporal and spatial interval, the less room for confounders (especially spontaneous remission) to interfere. It is equally important, for the time interval between administration of the treatment and cure to agree with the supposed mechanism of the treatment.

In some cases the *spatial* proximity between the site of administration and the outcome (see the oral

ulceration example below) may support causality – for example, thrombophlebitis at the site of injection of a cytotoxic drug. Again, the outcome need not be close to where the intervention was administered in order for the relationship to be causal, but spatial proximity generally leaves less room for confounders to interfere.

Dose responsiveness (Bradford Hill's 'Biological gradient')

Does the outcome change when the intensity of the intervention is altered (at least if the purported mechanism predicts such a relationship)? While the presence of a dose-response relationship does not always support causality (this guideline will not be applicable for 'all or none' causes), its absence *when expected* would lead us to doubt causality. Strongest 'dose-response' evidence comes when the process is reversible. For example, the risk of lung cancer is increased in smokers but is also reduced by a half in those who stop smoking at the age of 50 years and almost completely abolished in those who stop at the age of 30.³⁶

Mechanistic evidence

Direct evidence does not always tell us *how* the intervention caused the outcome and this makes the result difficult to generalize.³⁷ What happens in between the intervention and the outcome is, as far as this category is concerned, a 'black box' (Figure 1). For example, Doll and Hill's famous study of the relation between the number of cigarettes smoked and the incidence of lung cancer³⁸ did not refer in any way to what happens between inhalation of cigarette smoke and the development of tumours in the lung. This brings us to the second category of guidelines.

Mechanisms play several roles. First, we tend to feel more confident about a treatment if the mechanism can be explained. Moreover, understanding the mechanism guides our generalization of a tightly controlled study to a wider population. Also, evidence about mechanisms plays a major role in generating hypotheses that should be tested by 'direct' tests. However, these roles of mechanism must be clearly distinguished from its distinct potential role in *confirming* hypotheses.

Although we believe that mechanistic evidence can provide evidential support for a causal hy-

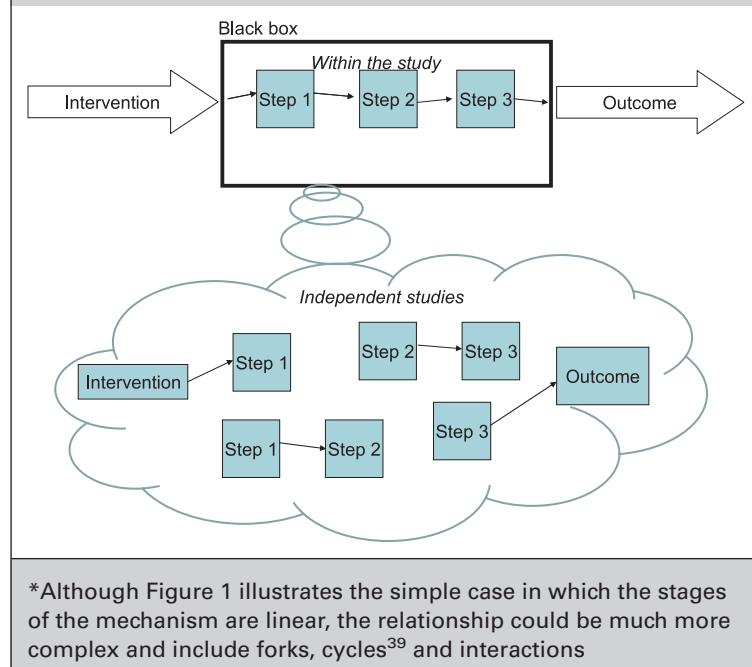
pothesis, two warnings are in order. Firstly, there is a difference between merely positing a mechanism (one can find a theory to explain almost anything) and providing sound evidence that there is a causal chain linking the intervention and the outcome. Secondly, appeal to mechanistic evidence has often justified the widespread use of treatments that turned out to be harmful.^{40–46} Likewise, the *absence* of a plausible mechanism has often been used as a justification to ignore useful therapies such as antisepsis⁴⁷ and peptic ulceration.⁴⁸ With this in mind, although we believe that mechanistic evidence cannot be ignored, we acknowledge that mechanistic evidence should always play a subsidiary confirmatory role *vis-à-vis* direct evidence.

Plausible mechanism

Is there evidence supporting the causal chain linking the intervention and the outcome? For example, trials testing the effect of ACE inhibitors on reduction in stroke mortality might include evidence that ACE inhibitors reduce blood pressure, that reduced blood pressure reduces the risk of stroke, and that the reduced incidence of stroke reduces mortality. Of course, each 'step' in the causal process is a new 'black box'. For example, the link between ACE inhibitors and blood pressure can be further decomposed into a series of steps, until (in a reductionist model) we bottom out at the molecular level. Bradford Hill, no doubt as an oversight, implied that plausibility was limited to 'biological plausibility'. Mechanisms of action can also be mechanical (as in the Mother's Kiss example below) or chemical (as in the oral ulceration example below).

We can envisage three 'levels' of evidential support from mechanistic evidence. Firstly, the direct study can also include studies of the causal links between the intervention and the outcome (Figure 1, top half). A second level of mechanistic evidence is when the purported mechanism of action has been demonstrated in other, independent studies (Figure 1, bottom half). For example, separate studies could establish a probable link between ACE inhibition and lower blood pressure. Obviously, having evidence for a part of the mechanism is not as strong as evidence for all the links in the causal chain.

Figure 1
Direct evidence of probabilistic dependence of outcome on intervention + evidence for the causal process*



The second level of mechanistic evidence is closest to Bradford Hill's 'Coherence', and we have kept this guideline separate.

Coherence

Does the causal hypothesis *cohere* with what is currently known, or is it contradicted by current knowledge? This is best explained by what happens when the evidence does not cohere. For example, the causal process by which a homeopathic remedy is purportedly effective (other than by 'placebo' effects) is not currently explicable by mainstream science. Given the numerous examples where treatments that seemed to cohere with current science that turned out to be harmful,^{40–46} and where treatments that seemed *not* to cohere with current science that turned out to be helpful,^{47,48} this guideline must be applied with care.

Parallel evidence

There are rarely cases where there is only a single piece of evidence for a causal claim. When assess-

ing whether an association is causal it is obviously necessary to consider *all* the relevant studies – this is the powerful idea underlying the importance of systematic reviews.

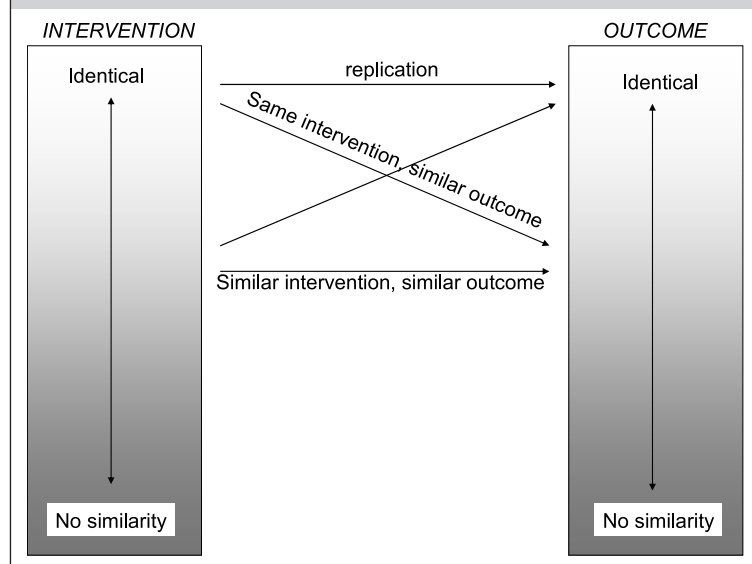
Replicability (Bradford Hill's 'Consistency')

A study can be replicated, which means that the same intervention is tested on a similar population, using the same outcome measure. In order to count as a replication, all the elements of the study must be kept constant as far as possible. Replicability is a central tenet of scientific method: if the experiment can be repeated and provides the same results, the chances that the original results arose due to confounding is reduced. If an experiment is not replicable, either something is wrong with the attempt to replicate it or the initial experiment must be questioned.

Similarity (of the study to other studies)

No two studies are absolutely identical, so similarities form a spectrum (Figure 2). Broadly speaking, there are several axes along which studies can differ. Firstly, the intervention can be different. If one NSAID reduced pain, we might have legitimately increased confidence that a new, similar drug would also reduce pain (although due caution would be warranted about potential adverse effects of the new drug and the benefit to harm balance). Other studies might use the same intervention and change the circumstances in which the intervention is administered. For example, we could test the intervention in a different (older or younger) population, conduct animal or *in vitro* experiments. We could also change the (geographical or socioeconomic) setting, or even the study type. Then, studies could use the same intervention but measure the outcome in different ways. If all the parallel studies gave similar results, then the causal hypothesis will be more strongly supported; if they don't, then we will have grounds to suspect either some of the parallel studies or the causal hypothesis itself. Of course, each piece of parallel evidence must be independently evaluated for validity (whether it satisfies the requirements inherent in our revised guidelines).

Figure 2
Types of similarities (the axis of 'similarity of circumstances' is omitted for simplicity)



Omitted guidelines

Besides *experiment*, which was absorbed in our first revised guideline, we also omitted *specificity*. Diseases usually have multiple causes and multiple effects, while most interventions also have multiple effects. In fact, Bradford Hill did not support this guideline with adequate examples, and in his description of multiple regression he admits that most diseases have multiple causes and that most causes have multiple effects.²² For example, the fact that smoking increases the risk of lung cancer in no way repudiates evidence that smoking causes other diseases. Similarly, the fact that Prozac might have a positive effect on depression does not reduce the force of the claim that it also cures premature ejaculation.

Tests of whether the Revised Bradford Hill guidelines deliver the verdict of strong evidence for causation, even if RCTs have not been conducted

A strict application of the EBM evidence hierarchy would deliver the verdict that the following treatments are supported by relatively *poor* evidence since they have not been tested in randomized

trials. After describing the examples, we shall evaluate whether the Revised Bradford Hill guidelines deliver a more reasonable verdict.

The Mother's Kiss

Glasziou *et al.*⁵ cite the following example:

A child presented with a plastic bead lodged high in one nostril. The doctor asked for forceps, but the nurse suggested trying the mother's kiss technique – occluding the unblocked nostril while the mother blows into the child's mouth. The bead was thus easily dislodged and retrieved.⁵

Most would agree that a single case (or at most a series of a few cases) would suffice to support claims that the mother's kiss caused the bead to dislodge.

Oral ulceration due to topical aspirin

Aronson and Hauben⁴⁹ have described several categories of adverse events related to drug administration that seem to require little more than anecdotal evidence to provide sufficiently strong evidence that the events are caused by adverse drug reactions. One of the categories is 'specific anatomical location or pattern of injury', in which:

... the location or pattern of injury is sufficiently specific to attribute the effect to the drug without the need for implicit judgment or formal investigation. The mechanism of injury can be related to physicochemical or pharmacological properties of the drug. Examples include extravasation reactions to cytostatic drugs and oral ulceration due to topical aspirin.⁴⁹

Here, anecdotal observations provide strong evidence that a particular drug caused an adverse event.

The Revised Bradford Hill guidelines deliver clear verdicts about the effectiveness of the Mother's Kiss and oral ulceration due to topical aspirin (Table 2). Admittedly the examples we chose are uncontroversial, but that is precisely why we chose them. Since nobody denies that these interventions caused their effects, while current hierarchies would deliver a poor 'grade' to their evidence base, it suggests that the Revised

Table 2
Applying the Revised Bradford Hill guidelines

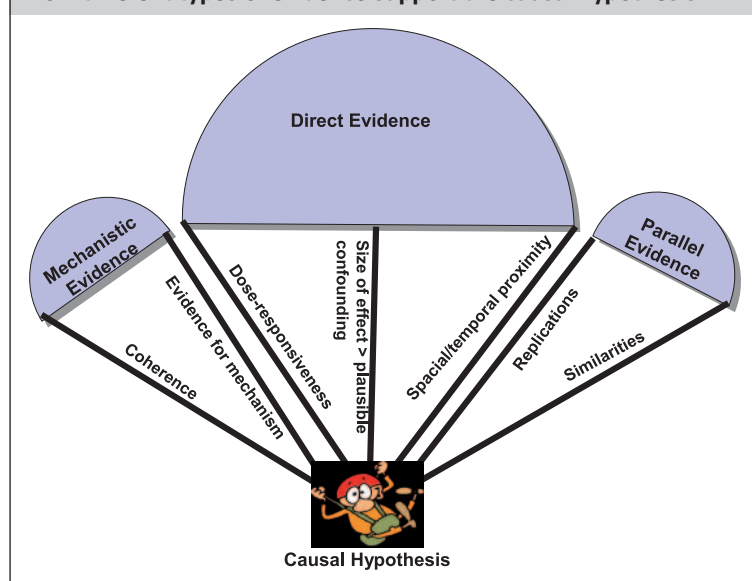
		<i>Mother's kiss</i>	<i>Oral ulceration</i>
<i>Direct</i>	1. Size of effect not attributable to plausible confounding 2. Appropriate temporal and/or spatial proximity 3. Dose-responsiveness and reversibility	Yes (dramatic effect; confounders highly unlikely) Yes (cure immediately follows the intervention and is spatially associated) Not tested and not relevant (might have been tested by varying levels of expiratory force)	Yes (dramatic effect; confounders highly unlikely) Yes (the effect is in immediate proximity to the intervention) Not tested (dose-responsiveness not tested; but subsequent healing suggested reversibility)
<i>Mechanistic</i>	4. Plausible mechanism of action 5. Coherence	Yes Yes (nothing contradicts the causal hypothesis)	Yes (acidic compound) Yes (nothing contradicts the causal hypothesis)
<i>Parallel</i>	6. Replicability 7. Similarity	Yes Not relevant	Not tested Yes (aspirin causes gastric erosions)
Total		5 'yes' (1, 2, 4, 5, 6) 2 'not relevant' or 'not tested' (3, 7)	5 'yes' (1, 2, 4, 5, 7) 2 'not relevant' or 'not tested' (3, 6)
VERDICT		5 out of 7 guidelines satisfied	5 out of 7 guidelines satisfied

guidelines can be useful tools for the future development and evolution of standards of medical evidence.

Conclusions: suggesting ways to revise current hierarchies of evidence

The original Bradford Hill Guidelines can be simplified (some of the guidelines can be omitted while others can be combined or modified) and organized into three categories: *direct*, *mechanistic* and *parallel* evidence. In their revised form they suggest two ways that can inform revisions to current hierarchies of evidence. Firstly, it is more important for 'direct' evidence to demonstrate that the effect size is greater than the combined influence of plausible confounders, than it is for the study to be experimental. This view is compatible with the spirit of EBM hierarchies: the motivation for placing RCTs at the pinnacle of evidence hierarchies is that they generally rule out more confounders than other study types. If an observational study reveals an effect large enough to swamp the effects of any additional confounding then other study designs must be regarded as on a par with RCTs. Likewise, RCTs must demonstrate effect sizes sufficiently large to rule out the combined effect of any inevitable bias. Secondly,

Figure 3
How different types of evidence support the causal hypothesis



the revised guidelines illustrate how different types of evidence can complement one another (Figure 3).^{50,51} Whereas a trial is often open to the objection that it is an anomaly or not generalizable, if we supplement the evidence from the trial with strong mechanistic and parallel evidence, it becomes increasingly difficult to question the results of the study and its applicability to a wider target population. A similar idea supports the use of systematic reviews, teleoanalysis³³ and the tenet of replicability in scientific method. These features of the guidelines make them particularly helpful where RCTs are unfeasible.

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Exhibit 4

Arch I. "Chip" Carson, M.D., Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW JERSEY

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IN RE JOHNSON & JOHNSON)
TALCUM POWDER PRODUCTS)
MARKETING, SALES) MDL NO.
PRACTICES, AND PRODUCTS) 16-2738 (FLW) (LHG)
LIABILITY LITIGATION)
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ALL CASES)
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Saturday, January 19, 2019
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Videotaped Deposition of ARCH I. "CHIP"
CARSON, M.D., Ph.D., held at the Marriott
Houston Medical Center, 6580 Fannin Street,
Houston, Texas, commencing at 9:02 a.m., on
the above date, before Michael E. Miller,
Fellow of the Academy of Professional
Reporters, Certified Court Reporter,
Registered Diplomate Reporter, Certified
Realtime Reporter and Notary Public.

— — —
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Arch I. "Chip" Carson, M.D., Ph.D.

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<p style="text-align: right;">Page 6</p> <p>1 DEPOSITION EXHIBITS</p> <p>2</p> <p>3 Exhibit 15 Handwritten List of 124</p> <p>4 Materials Reviewed by</p> <p>5 Dr. Carson</p> <p>6 Exhibit 16 1979 Chappell et al 130</p> <p>7 Publication</p> <p>8 Exhibit 17 2011 Reid et al Publication 159</p> <p>9 Exhibit 18 2011 Camargo et al 163</p> <p>10 Publication</p> <p>11 Exhibit 19 2013 Terry et al 192</p> <p>12 Publication</p> <p>13 Exhibit 20 2016 Cramer et al 195</p> <p>14 Publication</p> <p>15 Exhibit 21 IARC Classification Groups 225</p> <p>16 Document</p> <p>17 Exhibit 22 2017 Berge et al 243</p> <p>18 Publication</p> <p>19 Exhibit 23 2007 Langseth et al 247</p> <p>20 Publication</p> <p>21 Exhibit 24 2016 Schildkraut et al 271</p> <p>22 Publication</p> <p>23 Exhibit 25 Excerpt from IARC 289</p> <p>24 Monograph 93</p>	<p style="text-align: right;">Page 8</p> <p>1 PROCEEDINGS</p> <p>2 (January 19, 2019 at 9:02 a.m.)</p> <p>3 THE VIDEOGRAPHER: We are now</p> <p>4 on the record. My name is Doug</p> <p>5 Overstreet. I'm the videographer for</p> <p>6 Golkow Litigation Services. Today is</p> <p>7 January 19th, 2019. The time is</p> <p>8 9:02 a.m.</p> <p>9 This video deposition is being</p> <p>10 held in Houston, Texas in the matter</p> <p>11 of Talcum Powder Litigation MDL</p> <p>12 No. 2738.</p> <p>13 The deponent is Dr. Chip</p> <p>14 Carson.</p> <p>15 Will counsel please identify</p> <p>16 themselves for the record.</p> <p>17 MS. O'DELL: Leigh O'Dell,</p> <p>18 Beasley Allen, for the plaintiffs.</p> <p>19 DR. THOMPSON: Margaret</p> <p>20 Thompson, Beasley Allen, for the</p> <p>21 plaintiffs.</p> <p>22 MS. KLEVORN: Amanda Klevorn,</p> <p>23 Burns Charest, for the plaintiffs.</p> <p>24 MR. ZELLERS: Michael Zellers</p>
<p style="text-align: right;">Page 7</p> <p>1 REFERENCED EXHIBITS</p> <p>2</p> <p>3 NUMBER PAGE</p> <p>4 Exhibit 148</p> <p>5 Hopkins-28</p> <p>6 Exhibit 148</p> <p>7 Pier-47</p> <p>8 Exhibit 28</p> <p>9 P-346</p> <p>10 --o0o--</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 9</p> <p>1 for the Johnson & Johnson defendants.</p> <p>2 MS. McBETH: Katherine McBeth,</p> <p>3 Drinker Biddle & Reath, for the</p> <p>4 Johnson & Johnson defendants as well.</p> <p>5 MS. BOCKUS: Jane Bockus for</p> <p>6 Imerys.</p> <p>7 MR. DONATH: Jonathan Donath</p> <p>8 from Coughlin Duffy for Imerys.</p> <p>9 MS. APPEL: Renée Appel from</p> <p>10 Seyfarth Shaw for Personal Care</p> <p>11 Products.</p> <p>12 MS. TINSLEY: Caroline Tinsley,</p> <p>13 Tucker Ellis, for PTI Union, LLC and</p> <p>14 PTI Royston, LLC.</p> <p>15 THE VIDEOGRAPHER: The court</p> <p>16 reporter today is Mr. Mike Miller, and</p> <p>17 he will now swear in the witness.</p> <p>18 ARCH I. "CHIP" CARSON, M.D., Ph.D.,</p> <p>19 having been duly sworn,</p> <p>20 testified as follows:</p> <p>21 EXAMINATION</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. Can you state your name,</p> <p>24 please.</p>

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<p>1 A. Arch Carson.</p> <p>2 Q. You are a physician; is that</p> <p>3 right?</p> <p>4 A. I am.</p> <p>5 Q. A medical toxicologist?</p> <p>6 A. Yes.</p> <p>7 Q. We are here today to take your</p> <p>8 deposition in the talc MDL litigation</p> <p>9 proceedings; is that right?</p> <p>10 A. As far as I know, yes.</p> <p>11 Q. You are an expert witness for</p> <p>12 the plaintiffs in that litigation; is that</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. Did you receive a notice of</p> <p>16 deposition, which we'll mark as Exhibit 1, to</p> <p>17 appear here today?</p> <p>18 (Carson Deposition Exhibit 1</p> <p>19 marked.)</p> <p>20 A. Yes, I received a copy of this</p> <p>21 document.</p> <p>22 MS. O'DELL: And, Michael, just</p> <p>23 for the record, we just reassert all</p> <p>24 our previously served objections to</p>	<p>1 BY MR. ZELLERS:</p> <p>2 Q. As best we can, let me finish</p> <p>3 my question before you start to give your</p> <p>4 answer. I'll do the same and allow you to</p> <p>5 finish your answer before I ask you another</p> <p>6 question so our court reporter can take down</p> <p>7 what each of us say.</p> <p>8 Can you do that?</p> <p>9 A. Yes.</p> <p>10 Q. In response to the notice of</p> <p>11 deposition, which we've marked as Exhibit 1,</p> <p>12 have you brought with you certain documents</p> <p>13 here today?</p> <p>14 A. I have a collection of</p> <p>15 documents that in part respond to these</p> <p>16 requests, yes.</p> <p>17 Q. Do you have any documents in</p> <p>18 your possession that are responsive to the</p> <p>19 notice of deposition, Exhibit 1, that you</p> <p>20 have not brought here today?</p> <p>21 A. I would have to go through</p> <p>22 these things one by one, but --</p> <p>23 Q. You didn't do that before we</p> <p>24 came here today?</p>
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<p>1 the notice.</p> <p>2 MR. ZELLERS: Thank you.</p> <p>3 BY MR. ZELLERS:</p> <p>4 Q. You have given deposition</p> <p>5 testimony in the past; is that right?</p> <p>6 A. I have.</p> <p>7 Q. On how many occasions?</p> <p>8 A. Probably 30, 35.</p> <p>9 Q. You are familiar with the</p> <p>10 procedures we're going to follow today?</p> <p>11 A. More or less, I think.</p> <p>12 Q. If at any time I ask you a</p> <p>13 question and you don't understand it, tell me</p> <p>14 you don't understand it and I'll repeat it or</p> <p>15 rephrase it to try to make it clear to you.</p> <p>16 Can you do that?</p> <p>17 A. Yes.</p> <p>18 Q. If you answer a question that I</p> <p>19 ask or that any of the counsel ask, we're</p> <p>20 going to assume that you understood it; is</p> <p>21 that fair?</p> <p>22 MS. O'DELL: Object to form.</p> <p>23 A. That's fair.</p> <p>24 ///</p>	<p>1 A. I did, but the plaintiffs'</p> <p>2 attorneys --</p> <p>3 MS. O'DELL: Let me just stop</p> <p>4 you, Dr. Carson, just because</p> <p>5 discussing what we've discussed is not</p> <p>6 within the purview of this deposition.</p> <p>7 That's privileged. Let me just say --</p> <p>8 THE WITNESS: All right.</p> <p>9 MS. O'DELL: -- Dr. Carson, in</p> <p>10 response to the notice, has brought</p> <p>11 with him copies of the cited materials</p> <p>12 in his report, and that's in the</p> <p>13 binder that is to his left.</p> <p>14 He's brought with him copies of</p> <p>15 certain documents that were listed on</p> <p>16 his materials considered list. He</p> <p>17 doesn't have a physical copy of</p> <p>18 everything on his materials considered</p> <p>19 list.</p> <p>20 I brought today a thumb drive</p> <p>21 that has a copy of all the items on</p> <p>22 his materials considered list. If you</p> <p>23 would like access to that, it's</p> <p>24 available to you.</p>

4 (Pages 10 to 13)

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<p>1 And then in addition, he has 2 brought some additional materials that 3 he has reviewed since the service of 4 his report. 5 The only other item, as I 6 recall, on the notice of deposition 7 request for documents that has not 8 been brought to the deposition is 9 copies of invoices and Dr. Carson has 10 not sent us an invoice. That's why we 11 don't have a copy. 12 So to try to short-circuit 13 this, just to make sure since we made 14 decisions about what's produced and 15 what's not, I'll just say all that for 16 the record. And if you'd like that, 17 you're welcome to it. 18 BY MR. ZELLERS: 19 Q. Dr. Carson, you heard 20 Ms. O'Dell describe what you brought here 21 today. Is all of that accurate? 22 A. It is. 23 Q. Are you aware of there being 24 any documents or materials that are</p>	<p>1 Q. I'll ask you about the 2 attachments in a moment. 3 Does this report, 4 Deposition Exhibit 2, contain all of the 5 opinions that you intend to offer at any 6 trial or hearing of this matter? 7 A. In general, it contains all of 8 my opinions. I expect to expand on those 9 opinions possibly in this deposition or in 10 the future. 11 Q. Today's my opportunity to ask 12 you what your opinions are in this matter. 13 As of today, are the opinions 14 that you expressed to us set forth at any 15 trial or hearing in this matter, are they 16 contained in your report, Exhibit 2? 17 A. I have seen information that 18 has become available recently that I did not 19 have at that time this report was finalized, 20 and I have modified my opinions very slightly 21 as a result of that information. 22 Q. How have you modified your 23 opinions? 24 A. My opinions have essentially</p>
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<p>1 responsive to the deposition notice that you 2 have not brought with you here today? 3 A. No. 4 Q. I'm trying to understand what 5 counsel for plaintiffs, Ms. O'Dell, has said, 6 so let me ask you some questions. 7 You have brought with you today 8 in a binder some of the cited materials in 9 your report; is that right? 10 A. Yes. This is intended to be a 11 complete set of the cited references, with 12 one exception. 13 Q. When you say cited 14 references -- 15 A. From my report. 16 Q. Your expert report, we will 17 mark as Exhibit 2. 18 (Carson Deposition Exhibit 2 19 marked.) 20 BY MR. ZELLERS: 21 Q. Is Deposition Exhibit 2 your 22 report in this matter? 23 A. It is. It also has 24 attachments.</p>	<p>1 been strengthened as they relate to the 2 causation question between perineal talcum 3 powder use and the occurrence of ovarian 4 cancers. 5 Q. Other than you believing that 6 your opinions are strengthened with respect 7 to the association between perineal talcum 8 powder use and ovarian cancer, have your 9 opinions changed at all since you prepared 10 your report, Exhibit 2? 11 A. No. 12 Q. Are there any new or additional 13 opinions as of today that you expect to 14 testify to at trial or any hearing of this 15 matter other than your report, Exhibit 2, and 16 as you have qualified that report by stating 17 that your opinions on association are 18 stronger today? 19 A. No. 20 MS. O'DELL: Object to the 21 form. 22 BY MR. ZELLERS: 23 Q. Okay. Your report has a list 24 of references that begin on page 11.</p>

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<p style="text-align: right;">Page 18</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. What are the references? What</p> <p>4 do they relate to? And by that, I mean --</p> <p>5 I'm just trying to understand what this list</p> <p>6 is.</p> <p>7 A. This is a list of references</p> <p>8 from which I gleaned information that were</p> <p>9 important to my forming opinions regarding</p> <p>10 the question that was given to me, and they</p> <p>11 contribute to pieces of the report in various</p> <p>12 ways.</p> <p>13 They don't represent a complete</p> <p>14 review that I made in preparing my report,</p> <p>15 but all are important in some way in terms of</p> <p>16 coming to my conclusions.</p> <p>17 Q. Are the references that you</p> <p>18 list in your report from page 11 up and</p> <p>19 through page 16, are those the materials that</p> <p>20 you are relying on in terms of your opinions</p> <p>21 that you're expressing in your report?</p> <p>22 MS. O'DELL: Objection to form.</p> <p>23 A. Yes.</p> <p>24 ///</p>	<p style="text-align: right;">Page 20</p> <p>1 I produced a report that I</p> <p>2 thought was responsive to the question that</p> <p>3 was given to me by the plaintiffs' attorneys,</p> <p>4 and within that report I felt it necessary to</p> <p>5 cite specific key references that contributed</p> <p>6 to items in that report.</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. And those are --</p> <p>9 MS. O'DELL: Excuse me, sir.</p> <p>10 Are you finished, Dr. Carson?</p> <p>11 THE WITNESS: Yes.</p> <p>12 MS. O'DELL: Okay. Sorry.</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. Those are the items that you've</p> <p>15 listed under References; is that right?</p> <p>16 A. Yes.</p> <p>17 Q. Literature are other materials</p> <p>18 that you have reviewed but didn't rise to the</p> <p>19 level of you citing them as a reference for</p> <p>20 your report, correct?</p> <p>21 A. That is correct, but they do</p> <p>22 contribute information that I utilize in</p> <p>23 terms of the whole to formulate my opinions.</p> <p>24 Q. Let me mark several of the</p>
<p style="text-align: right;">Page 19</p> <p>1 BY MR. ZELLERS:</p> <p>2 Q. What, then, is the difference</p> <p>3 between the references to your report and</p> <p>4 Exhibit B, which has a caption, Literature?</p> <p>5 A. The Exhibit B represents a</p> <p>6 larger set of documents, including scientific</p> <p>7 literature, technical reports, and so forth</p> <p>8 that I reviewed in preparation of my report</p> <p>9 and the formation of my opinions; but they</p> <p>10 did not contain information that I felt</p> <p>11 necessary to cite in my report.</p> <p>12 Q. The literature that you cite to</p> <p>13 as Appendix B of your report are materials</p> <p>14 that you reviewed but are not the materials</p> <p>15 that you're specifically relying on. The</p> <p>16 materials that you're specifically relying on</p> <p>17 are set forth in your references list; is</p> <p>18 that right?</p> <p>19 MS. O'DELL: Excuse me. Object</p> <p>20 to the form, misstates his testimony.</p> <p>21 A. My opinions are based on my</p> <p>22 total review of the literature as well as my</p> <p>23 training, my professional experience and many</p> <p>24 other factors.</p>	<p style="text-align: right;">Page 21</p> <p>1 attachments to your report as separate</p> <p>2 exhibits.</p> <p>3 (Carson Deposition Exhibit 3</p> <p>4 marked.)</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. Exhibit 3 is your curriculum</p> <p>7 vitae that was attached to your report; is</p> <p>8 that right?</p> <p>9 A. Yes.</p> <p>10 (Carson Deposition Exhibit 4</p> <p>11 marked.)</p> <p>12 BY MR. ZELLERS:</p> <p>13 Q. Exhibit 4 is a copy of your</p> <p>14 literature list that we just discussed that</p> <p>15 is in your report; is that right?</p> <p>16 A. Yes.</p> <p>17 MS. O'DELL: Thank you.</p> <p>18 BY MR. ZELLERS:</p> <p>19 Q. The one difference with</p> <p>20 Exhibit 4, your literature list that's</p> <p>21 attached to your report as Appendix B is not</p> <p>22 numbered. I've gone ahead and numbered the</p> <p>23 pages on Exhibit 4, your literature list, in</p> <p>24 case we want to refer to a specific page.</p>

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<p>1 Today, when I refer to 2 products, talc products, baby powder or 3 Shower to Shower, I'm referring to the baby 4 powder product manufactured by Johnson & 5 Johnson Consumer Products Inc. and the Shower 6 to Shower product formerly manufactured by 7 Johnson & Johnson Consumer Products Inc. 8 Do you understand that? 9 A. Yes. 10 Q. Is your report, Exhibit 2, 11 accurate? 12 A. I believe so. 13 Q. Do you believe it's complete? 14 A. In terms of its focus, yes. 15 Q. What do you mean in terms of 16 its focus? 17 A. It covers specific aspects of a 18 larger question, and regarding those specific 19 aspects, I believe it is complete. 20 Q. It covers the aspects of the 21 question that you intend to offer opinions 22 on, correct? 23 A. That is correct. 24 Q. What is the question that was</p>	<p>1 binder of materials; is that right? 2 A. Yes. 3 Q. The binder of materials, did 4 you prepare that, or was it prepared for you? 5 A. Well, I uploaded documents to a 6 share file, and the plaintiffs' attorneys 7 were kind enough to print those for me and 8 assemble them in the binder. 9 Q. In addition, you have brought 10 with you a stack of eight or so additional 11 references that you have on the table in 12 front of you; is that right? 13 A. Yes. 14 Q. Are those materials that were 15 cited either as references in your report or 16 in the literature section of your report? 17 A. I think they're all included in 18 one or the other of those lists. 19 Q. Your testimony under oath is 20 that all of the additional materials you 21 brought here today are referred to either in 22 your reference list, which is -- begins at 23 page 11 of your report, or your literature 24 list, which we've marked as Exhibit 4 and is</p>
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<p>1 given to you by counsel for plaintiffs in 2 this litigation? 3 A. The question is do the -- does 4 the habitual use of talcum powder products 5 cause ovarian cancer. 6 Q. Were you given any other 7 questions to answer or opine on in this 8 litigation? 9 A. Not specifically. 10 Q. What do you understand habitual 11 use of talcum powder to refer to? 12 A. It means routine use, periodic 13 use. 14 Q. Over any period of time? 15 A. Over an extended period of 16 time. 17 Q. What is an extended period of 18 time? 19 A. Months or years. 20 Q. Any other definition that you 21 have of habitual use? 22 A. No. 23 Q. Today, in response to the 24 notice of deposition, you did bring the</p>	<p>1 Exhibit B to your report; is that right? 2 MS. O'DELL: Objection to the 3 form. 4 Go ahead. 5 A. There are a couple of new 6 articles here that were not available at the 7 time that I submitted my report, and I 8 believe the literature list was also created. 9 BY MR. ZELLERS: 10 Q. Were those new materials 11 provided to you by plaintiffs' counsel or are 12 those materials that you did some type of 13 literature search and found? 14 A. One of them was provided to me 15 by plaintiffs' counsel, but I was aware that 16 it was coming. And -- actually, two of them 17 were provided by plaintiffs' counsel. 18 Q. All right. The two additional 19 documents that were provided to you by 20 plaintiffs' counsel, can you show those to 21 me? 22 A. Okay. One is the Longo report. 23 Q. We will mark as 24 Deposition Exhibit 5 the Longo report dated</p>

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<p style="text-align: right;">Page 26</p> <p>1 January 15th of 2009 [sic]. 2 (Carson Deposition Exhibit 5 3 marked.) 4 A. The other is the recent 5 Fletcher, et al article. 6 (Carson Deposition Exhibit 6 7 marked.) 8 BY MR. ZELLERS: 9 Q. The Fletcher article dated 10 January 3rd of 2019 we'll mark as Exhibit 6. 11 This is an article from Reproductive 12 Sciences; is that right? 13 A. Yes. And I actually have a 14 third. 15 Q. All right. You have a third 16 article that was provided to you by 17 plaintiffs' counsel? 18 A. Yes. 19 (Carson Deposition Exhibit 7 20 marked.) 21 BY MR. ZELLERS: 22 Q. Let's mark that as 23 Deposition Exhibit 7. Can you tell us what 24 article that is?</p>	<p style="text-align: right;">Page 28</p> <p>1 Ph.D.; is that right? 2 A. Yes. 3 Q. What additional articles have 4 you brought here with you today separate and 5 apart from your binder of materials? 6 A. There's a copy of the IARC 7 monographs preamble. 8 Q. For what purpose did you bring 9 that article? 10 A. This discusses the general 11 process that IARC uses in approaching a 12 putative carcinogenic material. 13 Q. That has previously been marked 14 as Plaintiff Exhibit P-346 in another 15 proceeding; is that right? 16 A. I don't know. 17 Q. Well, the document we're 18 looking at has that exhibit sticker on it; is 19 that right? 20 A. It does. 21 Q. What else have you brought here 22 with you today? 23 A. This is an article from 24 The Lancet from 1952 titled Value of Modified</p>
<p style="text-align: right;">Page 27</p> <p>1 A. This is a meta-analysis. 2 It's -- the title is Systematic Review and 3 Meta-Analysis of the Association Between 4 Perineal Use of Talc and Risk of Ovarian 5 Cancer. The lead author is Mohamed Taher. 6 Q. The Taher paper we have marked 7 as Exhibit 7; is that right? 8 A. Yes. 9 Q. This is something that you were 10 provided by plaintiffs' counsel; is that 11 right? 12 A. Yes. 13 Q. Exhibit 6, Reproductive 14 Sciences, are you familiar with that journal? 15 A. I'm aware that it exists. 16 Q. Do you review that journal on a 17 regular basis as a part of your clinical and 18 research activities? 19 A. No, I don't. 20 Q. Is Reproductive Sciences a 21 peer-reviewed journal? 22 A. I believe it is. 23 Q. The Exhibit 6 has as a 24 corresponding author, Dr. Saed, S-A-E-D, a</p>	<p style="text-align: right;">Page 29</p> <p>1 Starch as a Substitute for Talc, and the 2 first author is J.D.P. Graham. 3 Q. Why did you bring that article? 4 A. This is an older article that 5 discusses the suitability of substituting 6 cornstarch materials for talc due to 7 perceived issues with talc. 8 Q. Is this an article that you had 9 cited previously, either in your references 10 or your list of literature? 11 A. I did not cite it in my report. 12 I don't know -- I don't recall if it's in the 13 literature list or not. 14 (Carson Deposition Exhibit 8 15 marked.) 16 BY MR. ZELLERS: 17 Q. Why did you decide to bring 18 that with you here today? 19 A. It is in the literature list. 20 I ran across it last night, and 21 I thought I might need to refer to it during 22 the deposition. 23 Q. What other documents or 24 materials have you brought other than your</p>

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<p>1 binder of materials?</p> <p>2 A. I have here a copy of the</p> <p>3 recent Canadian position on the safety of</p> <p>4 talcum powder and its relationship to ovarian</p> <p>5 cancer.</p> <p>6 Q. When did you review that</p> <p>7 document?</p> <p>8 A. A couple weeks ago, I think.</p> <p>9 Q. Is that a document that you</p> <p>10 were provided by plaintiffs' counsel?</p> <p>11 A. It was.</p> <p>12 Q. Can I see the document, please?</p> <p>13 We'll mark the draft screening assessment</p> <p>14 from Health Canada dated December 18th of</p> <p>15 2018 as Exhibit 9.</p> <p>16 (Carson Deposition Exhibit 9</p> <p>17 marked.)</p> <p>18 BY MR. ZELLERS:</p> <p>19 Q. Any other documents?</p> <p>20 A. I have a copy of the letter</p> <p>21 from the FDA from April 1st, 2014 responding</p> <p>22 to positions -- petitions for labeling.</p> <p>23 Q. This is a letter that has a</p> <p>24 stamp on it on the first page, April 1st,</p>	<p>1 talcum powder and ovarian cancer, is</p> <p>2 something that you undertook when you were</p> <p>3 retained by plaintiffs' counsel and asked to</p> <p>4 address the question they gave to you?</p> <p>5 A. Yes, it is.</p> <p>6 Q. We will mark the article by</p> <p>7 Blount as Exhibit 11.</p> <p>8 (Carson Deposition Exhibit 11</p> <p>9 marked.)</p> <p>10 BY MR. ZELLERS:</p> <p>11 Q. And you have one more; is that</p> <p>12 right?</p> <p>13 A. Yes, one more, which is -- this</p> <p>14 is an article from the American Journal of</p> <p>15 Obstetrics and Gynecology from 1974 titled</p> <p>16 The Ovarian Mesothelioma. It's authored by</p> <p>17 Parmley and Woodruff.</p> <p>18 Q. We'll mark that as Exhibit 12.</p> <p>19 (Carson Deposition Exhibit 12</p> <p>20 marked.)</p> <p>21 BY MR. ZELLERS:</p> <p>22 Q. Exhibit 12, is this an article</p> <p>23 that was cited previously by you in either</p> <p>24 your references or your literature list?</p>
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<p>1 2014, from -- or strike that -- to</p> <p>2 Dr. Epstein from the FDA; is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Let's mark that as Exhibit 10.</p> <p>5 (Carson Deposition Exhibit 10</p> <p>6 marked.)</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. What else?</p> <p>9 A. I have an article authored by</p> <p>10 A.M. Blount which is titled Amphibole Content</p> <p>11 of Cosmetic and Pharmaceutical Talcs that was</p> <p>12 published in Environmental Health</p> <p>13 Perspectives in 1991.</p> <p>14 Q. Is that a journal that you</p> <p>15 review on a regular basis as part of either</p> <p>16 your clinical practice or your research</p> <p>17 activities?</p> <p>18 A. That one I do look at pretty</p> <p>19 much.</p> <p>20 Q. Is this an article you were</p> <p>21 aware of back in 1991?</p> <p>22 A. No. At least I don't recall.</p> <p>23 Q. Is it fair that your review of</p> <p>24 this literature, the literature relating to</p>	<p>1 A. Yes.</p> <p>2 Q. For what -- strike that.</p> <p>3 Is this a document that you</p> <p>4 chose to bring today or were you provided it</p> <p>5 by plaintiffs' counsel?</p> <p>6 A. This is another one I ran</p> <p>7 across last night and decided to bring along</p> <p>8 to the depo.</p> <p>9 Q. Same questions with respect to</p> <p>10 the Blount article, Exhibit 11: Is this an</p> <p>11 article you cite in your references or</p> <p>12 literature?</p> <p>13 A. In the literature, yes.</p> <p>14 Q. For what purpose have you</p> <p>15 brought this with you today?</p> <p>16 A. I thought I might want to refer</p> <p>17 to it in response to questions here.</p> <p>18 Q. Exhibit 10, the letter from the</p> <p>19 FDA to Dr. Epstein, April of 2014, for what</p> <p>20 purpose have you brought that here with you</p> <p>21 today?</p> <p>22 A. I thought I might want to refer</p> <p>23 to it in response to questioning.</p> <p>24 Q. The documents that you have</p>

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<p>1 brought here with you today are documents 2 that you wanted to have available to try to 3 respond to the questions that I may ask you? 4 A. Yes. 5 Q. These documents you all 6 believe -- strike that. 7 The documents that you've 8 identified and you've brought with you -- 9 have brought with you today, you believe 10 those are supportive of the opinions that you 11 are rendering in this matter; is that right? 12 A. Yes. 13 Q. The documents on your 14 literature list, what we have marked as 15 Exhibit 4, are those documents that were 16 provided to you by plaintiffs' counsel? 17 A. Some were. 18 Q. The documents on this list that 19 were not provided by plaintiffs' counsel, did 20 you find those through a literature search? 21 A. Yes. 22 Q. Are you able to distinguish for 23 us which documents on your literature list, 24 Exhibit 4, came from plaintiffs' counsel and</p>	<p>1 wouldn't be able to tell you for sure. I'm 2 sure I ran across these in my own literature 3 search. 4 Q. Deposition Exhibit 13, we will 5 mark the thumb drive that plaintiffs' counsel 6 has brought here today. 7 (Carson Deposition Exhibit 13 8 marked.) 9 BY MR. ZELLERS: 10 Q. Do you, Dr. Carson, have an 11 understanding of what's on the thumb drive 12 we've marked as Exhibit 13? 13 A. My understanding is this is 14 copies of the documents on the literature 15 list. 16 Q. When were you first retained by 17 anyone regarding the talc/ovarian cancer 18 litigation? 19 A. In October of 2018. 20 Q. Who contacted you? 21 A. I was contacted by an attorney 22 named Russ Abney. 23 Q. Who is Mr. Abney, if you know? 24 A. Mr. Abney is a lawyer who used</p>
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<p>1 which items on the literature list you came 2 up with? 3 A. To some extent. 4 Q. So if we went through item by 5 item, you believe you could distinguish 6 between what was provided to you by 7 plaintiffs and what you found on your own? 8 A. For some, but not all of them. 9 Q. Have you reviewed all of the 10 materials that are listed on your literature 11 list? 12 A. I have reviewed all of them, 13 yes. 14 Q. Have you reviewed all of the 15 materials that are on your reference list? 16 A. Yes. 17 Q. The materials on your reference 18 list, is it the same that some were provided 19 to you by plaintiffs' counsel and some you 20 found on your own? 21 A. I think there may be one or two 22 references that I didn't have before I saw 23 them in the share file that may have been 24 provided by plaintiffs' counsel, but I</p>	<p>1 to work in the Houston area and with whom I 2 had some dealings years ago; and since that 3 time he has become involved in this talc 4 litigation in some way, was aware of me as a 5 potential expert witness, and contacted me 6 regarding my interest and availability. 7 Q. What matters have you worked on 8 with Mr. Abney in the past? 9 A. I think it would have been back 10 in the 1990s, and I frankly don't recall what 11 cases we worked on, but there were one or 12 maybe two cases. 13 Q. When in October of 2018 were 14 you contacted by Mr. Abney? 15 MS. O'DELL: Object to the 16 form. 17 A. I believe it was either the 18 14th or 15th of October. 19 BY MR. ZELLERS: 20 Q. How do you remember with that 21 precision? 22 A. I have an e-mail that relates 23 to a phone call which was our initial 24 contact.</p>

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<p style="text-align: right;">Page 38</p> <p>1 Q. Mr. Abney at some point asked 2 you to address the question that you told us 3 before: Does the habitual use of talcum 4 powder cause ovarian cancer? 5 Is that right? 6 MS. O'DELL: Object to the 7 form. 8 A. Well, he talked to me generally 9 about the case that was proceeding, and I 10 discussed with him what my understanding of 11 those things was and what the kind of 12 opinions I would be able to render would be. 13 And he suggested that he set up a meeting 14 between me and members of plaintiffs' 15 counsel. 16 BY MR. ZELLERS: 17 Q. When Mr. Abney called you 18 middle of October of 2018, talcum powder and 19 any relationship or association that it may 20 have to ovarian cancer had not been a focus 21 of your research or study; is that right? 22 A. That's right. 23 Q. It had not been a part of your 24 clinical practice, right?</p>	<p style="text-align: right;">Page 40</p> <p>1 doing a review? What does that mean? 2 A. Well, I felt that I was hired 3 as a witness at that point and that's when I 4 would begin my billable hours on this case. 5 Q. When was that? Sometime in 6 later October of -- late October of 2018? 7 A. It was within a few days after 8 our first meeting, still in October. 9 Q. What did you do to answer the 10 question? What was your methodology? 11 A. Well, initially I decided to do 12 a general literature search on the question 13 to see what research had been performed, what 14 reports had been written, what the quality of 15 that research was. 16 Q. When did you start that? 17 A. Immediately. I was curious. 18 I began to assemble the 19 available literature and review it on a 20 piecemeal basis through the subsequent time 21 period; the next couple of weeks I reviewed a 22 lot of it. 23 Q. What did you search for when 24 you did this general literature search?</p>
<p style="text-align: right;">Page 39</p> <p>1 A. That's correct. 2 Q. When did you meet with the 3 larger group of plaintiffs' counsel? 4 A. I believe we had a telephone 5 meeting on the 16th of October. I'm not 6 sure. I have to -- 7 Q. That's -- right now I just want 8 estimates. 9 A. Okay. 10 Q. And so I don't -- as long as 11 you're reasonably comfortable that it was in 12 that time frame. 13 A. It was mid October. 14 Q. That's fine. 15 When were you asked the 16 question that the plaintiffs' lawyers wanted 17 you to try to answer in this litigation? 18 A. Well, after the meeting we 19 parted ways and then made contact again a few 20 days later, and I was told that they were 21 interested in me going ahead and doing a 22 review and starting to establish opinions. 23 Q. What do you mean by they 24 authorized you or were comfortable with you</p>	<p style="text-align: right;">Page 41</p> <p>1 A. I searched under various search 2 terms, including "talc," including "ovarian 3 cancer," the relationship between the two. 4 As I became more familiar with the 5 literature, I expanded that search into other 6 topics. 7 As I became -- I was already 8 aware of issues related to the inclusion of 9 asbestos in talc deposits, and so I expanded 10 my search into that part of the literature 11 that relates to asbestos in talc or asbestos 12 in ovarian cancer. 13 As I felt my opinions would 14 need to extend into cancer and carcinogenesis 15 in general, I did some search into ovarian 16 cancer specifically and general 17 carcinogenesis to see what the current state 18 of the art was regarding that in the 19 literature. 20 I looked at some issues of 21 mining practices. 22 I looked at the Johnson & 23 Johnson website. There's a webpage regarding 24 talc and ovarian cancer that I looked at.</p>

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<p>1 I looked through old notes and 2 lecture files that I had for information that 3 I've used or accessed previously in my 4 professional capacity for information that 5 was pertinent. 6 Just a very dendritic kind of 7 extensive search. 8 Q. You reviewed these materials 9 that you have told us about and then did you 10 prepare your report? 11 A. At that point I -- well, the 12 literature review took several stages. 13 Typically when you perform a review like 14 this, you end up with a -- I do a very 15 general sort of approach to a review, so I 16 get much more than will be pertinent to my 17 review eventually. 18 I find that a valuable approach 19 because it allows me to find things I 20 wouldn't otherwise find or look for or know 21 to look for. 22 And then I'm able to cull 23 through that information and discard pieces 24 of the search materials that are not relevant</p>	<p>1 review of draft versions of my report and 2 comments, in particular -- 3 Q. Don't tell me about the 4 comments. 5 A. Okay. 6 Q. I don't want to know what the 7 lawyers may have told you. 8 Did the comments come from the 9 lawyers for plaintiffs or did they come from 10 other people? 11 A. They came from the lawyers. 12 They also came from a few of my colleagues. 13 Q. Did you share your report with 14 some of your colleagues? 15 A. I let a few people read it and 16 I talked to them about it. 17 Q. Are the opinions your opinions? 18 A. Yes, they are. 19 Q. Have you told me, you know, 20 generally what you have done to formulate 21 your opinions in this matter? 22 A. Yes, I think so. 23 Q. You did all of this over a 24 30-day period; is that right?</p>
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<p>1 or interesting to me and then refine my 2 search and redo it, extending it into 3 different areas that have now become 4 pertinent in my opinion, until I satisfy 5 myself that I have pretty much covered the 6 waterfront so to speak in terms of a 7 literature review. 8 Q. You did your literature review. 9 You reviewed the Johnson & Johnson website 10 and the other materials that you have told us 11 about. 12 Did you then formulate your 13 opinions and set them down in your report 14 which we marked as Exhibit 2? 15 A. I did. I began writing as I 16 reviewed the literature and continued to take 17 notes which, through a continuous editing 18 process, eventually became my report. 19 Q. Did you prepare your report? 20 A. I did. 21 Q. Did anyone assist you in the 22 preparation of your report? 23 A. No one assisted me in the 24 preparation of my report. I did receive</p>	<p>1 A. Yes. 2 Q. All right. You have no 3 invoices, correct? 4 A. That's correct. 5 Q. Is it typical that you'll work 6 on a matter for some number of months and not 7 generate any invoices? 8 A. Yes. 9 Q. You are billing your time at 10 what rate? 11 A. \$450 per hour. 12 Q. Can you estimate for us the 13 number of hours that you have spent doing 14 your literature review, formulating your 15 opinions, and writing your report? 16 A. There's still some tallying I 17 need to do from my calendar, but it's between 18 150 and 180 hours. 19 Q. Does that include your meetings 20 and communications with plaintiffs' counsel? 21 A. Yes, that's up until today. 22 Q. Other than meeting with 23 Mr. Abney or talking with Mr. Abney -- did 24 you ever meet with Mr. Abney face-to-face?</p>

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<p>1 A. No.</p> <p>2 Q. What other plaintiff lawyers</p> <p>3 have you met with or talked with as part of</p> <p>4 your formulating your opinions and doing your</p> <p>5 literature review?</p> <p>6 A. We've had a number of</p> <p>7 conference calls where there were several of</p> <p>8 these attorneys' colleagues on the line, but</p> <p>9 in terms of in-person meetings, those have</p> <p>10 been with Ms. O'Dell and Ms. Thompson,</p> <p>11 Dr. Thompson.</p> <p>12 Q. How many meetings have you had</p> <p>13 with Ms. O'Dell?</p> <p>14 A. Three.</p> <p>15 Q. How many meetings have you had</p> <p>16 with Dr. Thompson?</p> <p>17 A. Three.</p> <p>18 Q. Did you know Dr. Thompson</p> <p>19 before you were retained in this matter?</p> <p>20 A. I did not.</p> <p>21 Q. Any other plaintiff lawyers in</p> <p>22 this litigation that you are aware of --</p> <p>23 strike that.</p> <p>24 Any other plaintiff lawyers in</p>	<p>1 A. I have not had any discussions</p> <p>2 with Dr. Dydek. We may have met previously,</p> <p>3 but I don't recall.</p> <p>4 Q. Any previous meeting with</p> <p>5 Dr. Dydek, did it relate to this litigation?</p> <p>6 A. No.</p> <p>7 Q. Did it relate to expert witness</p> <p>8 work that you were doing?</p> <p>9 A. No.</p> <p>10 Q. Do you know what the</p> <p>11 relationship is, if any, between Dr. Thompson</p> <p>12 and Dr. Dydek?</p> <p>13 A. I don't know of any</p> <p>14 relationship outside of his work as an expert</p> <p>15 witness in related litigation.</p> <p>16 Q. Dr. Crowley, do you know</p> <p>17 Michael Crowley?</p> <p>18 A. I know of Dr. Crowley.</p> <p>19 Q. Did you know of Dr. Crowley</p> <p>20 before you were retained in the talcum powder</p> <p>21 litigation?</p> <p>22 A. No.</p> <p>23 Q. Have you ever met with</p> <p>24 Dr. Crowley?</p>
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<p>1 this matter that you've had communications</p> <p>2 with other than what you have told us?</p> <p>3 A. No.</p> <p>4 Q. Do you have any social</p> <p>5 relationship with any of the plaintiffs'</p> <p>6 counsel?</p> <p>7 A. No.</p> <p>8 Q. Your relationship with</p> <p>9 Dr. Thompson is just the three meetings that</p> <p>10 you have been involved in with her?</p> <p>11 A. Well, we've exchanged e-mail</p> <p>12 communications, but other than that, no.</p> <p>13 Q. Have you met with or talked</p> <p>14 with any other expert witness for plaintiffs?</p> <p>15 A. No, I have not.</p> <p>16 Q. Do you know who Thomas Dydek</p> <p>17 is?</p> <p>18 A. Yes.</p> <p>19 Q. Who is Thomas Dydek?</p> <p>20 A. He is a toxicologist.</p> <p>21 Q. Where does he practice?</p> <p>22 A. I don't recall.</p> <p>23 Q. Have you had any discussions</p> <p>24 with Dr. Dydek?</p>	<p>1 A. I have not.</p> <p>2 Q. Ever talked with Dr. Crowley?</p> <p>3 A. I have not.</p> <p>4 Q. You reviewed his report as part</p> <p>5 of your review in this matter; is that right?</p> <p>6 A. That's correct.</p> <p>7 Q. Do you know who any of the</p> <p>8 other experts are in this litigation for</p> <p>9 plaintiffs?</p> <p>10 A. Well, I know there are a number</p> <p>11 of people who have generated reports that I</p> <p>12 have also reviewed.</p> <p>13 Q. What reports have you reviewed</p> <p>14 from plaintiffs' other experts?</p> <p>15 A. Well, I've reviewed several</p> <p>16 reports from Dr. Longo, who's done work on</p> <p>17 the presence of asbestos in talc products and</p> <p>18 related things. I think he's the only other</p> <p>19 expert that I'm aware of at this point.</p> <p>20 Q. Well, you're aware of</p> <p>21 Dr. Crowley?</p> <p>22 A. Well, Dr. Crowley, Dr. Longo,</p> <p>23 and Dr. Dydek that you mentioned before.</p> <p>24 Q. Have you reviewed any reports</p>

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<p style="text-align: right;">Page 50</p> <p>1 or transcripts from Dr. Dydek?</p> <p>2 A. Yes, I reviewed an expert</p> <p>3 report that he provided before I got involved</p> <p>4 in this case.</p> <p>5 Q. Did you review that report</p> <p>6 before you prepared your report?</p> <p>7 A. Yes.</p> <p>8 Q. Did you review Dr. Crowley's</p> <p>9 report before you prepared your report?</p> <p>10 A. Yes.</p> <p>11 Q. And you reviewed Dr. Longo's</p> <p>12 report before you prepared your report; is</p> <p>13 that right?</p> <p>14 A. I've reviewed one report.</p> <p>15 There was another one that became available</p> <p>16 after.</p> <p>17 Q. The second report is what you</p> <p>18 brought here with you today and we marked as</p> <p>19 Exhibit 5; is that right?</p> <p>20 A. Yes.</p> <p>21 Q. Any other plaintiff experts</p> <p>22 that you're aware of?</p> <p>23 A. Not that I can think of, no.</p> <p>24 Q. Any other reports from</p>	<p style="text-align: right;">Page 52</p> <p>1 that you're aware of?</p> <p>2 A. No.</p> <p>3 Q. Are you aware of any of the</p> <p>4 experts for defendants in the talcum powder</p> <p>5 litigation?</p> <p>6 A. No.</p> <p>7 Q. Have you reviewed any reports</p> <p>8 from any of the experts in the talcum powder</p> <p>9 litigation?</p> <p>10 A. I have not.</p> <p>11 Q. Have you reviewed any of the</p> <p>12 transcripts of defense experts in the talcum</p> <p>13 powder litigation?</p> <p>14 A. I've reviewed some deposition</p> <p>15 transcripts of various witnesses.</p> <p>16 Q. Those witnesses are all listed</p> <p>17 in either your references or your literature;</p> <p>18 is that right?</p> <p>19 A. Yes.</p> <p>20 Q. Did you review the entire</p> <p>21 transcripts of the witnesses that you've</p> <p>22 identified?</p> <p>23 A. I think for the most part I</p> <p>24 would say yes.</p>
<p style="text-align: right;">Page 51</p> <p>1 plaintiffs' experts that you have reviewed?</p> <p>2 A. Well, there's a -- there is an</p> <p>3 article that's been submitted for publication</p> <p>4 which I consider a piece of the scientific</p> <p>5 literature. You mentioned Dr. Saed earlier,</p> <p>6 and I know that he has a relationship with</p> <p>7 this case as well.</p> <p>8 Q. What is his relationship with</p> <p>9 this case, Dr. Saed?</p> <p>10 A. He's provided some work at the</p> <p>11 request of the attorneys here.</p> <p>12 Q. Have you reviewed that work?</p> <p>13 A. That's the subject of several</p> <p>14 articles he's published previously, he and</p> <p>15 his colleagues, as well as the additional one</p> <p>16 that I brought today.</p> <p>17 Q. Other than the articles that</p> <p>18 you have listed on your reference and</p> <p>19 literature list and the Saed article that you</p> <p>20 brought with you today, are you aware of any</p> <p>21 other work that Dr. Saed has done in this</p> <p>22 matter?</p> <p>23 A. No.</p> <p>24 Q. Any other plaintiff experts</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Did you review the exhibits to</p> <p>2 those depositions?</p> <p>3 A. Yes. If they were provided to</p> <p>4 me, I did, yes.</p> <p>5 Q. Did you believe that it was</p> <p>6 your job to do an independent assessment as</p> <p>7 to whether or not the habitual use of talcum</p> <p>8 powder causes or can cause ovarian cancer?</p> <p>9 MS. O'DELL: Object to the</p> <p>10 form.</p> <p>11 A. Could you repeat the question,</p> <p>12 please.</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. Sure.</p> <p>15 Plaintiffs asked you to --</p> <p>16 strike that.</p> <p>17 Plaintiffs' counsel asked you</p> <p>18 to answer that question; is that right?</p> <p>19 A. Yes.</p> <p>20 Q. You understood that they were</p> <p>21 looking to develop an association or a causal</p> <p>22 relationship between the habitual use of</p> <p>23 talcum powder and ovarian cancer, correct?</p> <p>24 A. Yes.</p>

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<p>1 MS. O'DELL: Object to the 2 form. 3 Excuse me, I'm sorry, 4 gentlemen. Give me just one second to 5 object if I need to. 6 THE WITNESS: Sure. 7 MS. O'DELL: Thank you. 8 BY MR. ZELLERS: 9 Q. Did you consider the literature 10 and the sources that refuted that association 11 or causal relationship? 12 A. I tried to consider all the 13 available literature. 14 Q. When you wrote your report 15 setting forth your opinions, did you set 16 forth the sources that refuted the 17 propositions you were making? 18 A. I cited several sources that on 19 the surface might seem to refute my opinions. 20 Q. And you believe that is 21 contained in your report which we marked as 22 Exhibit 2; is that right? 23 A. Yes. 24 Q. Have you been involved in any</p>	<p>1 A. Probably 5%. 2 Q. What percent of your income 3 comes from the work that you do as a 4 consultant? 5 A. Of course it varies quite a bit 6 from moment to moment, but it would be less 7 than 10%. 8 Q. Have you ever testified at 9 trial? 10 A. Yes. 11 Q. On how many occasions? 12 A. Probably ten. 13 Q. The 30 to 35 depositions that 14 you've given previously, those have been in 15 the context of you providing litigation 16 consulting services; is that right? 17 A. In terms of expert testimony, 18 yes. 19 Q. The trial appearances that 20 you've made, are those also in your capacity 21 as an expert witness? 22 A. Yes. 23 Q. Have you been involved in other 24 litigations?</p>
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<p>1 other talcum powder litigation other than 2 this talc MDL matter that Mr. Abney talked to 3 you about? 4 A. No, I haven't. 5 Q. In the 30 to 35 occasions that 6 you've testified in the past, have any of 7 those been on issues relating to talcum 8 powder and any association between talcum 9 powder and ovarian cancer? 10 A. No. 11 Q. You are not an expert in 12 asbestos, correct? 13 MS. O'DELL: Object to the 14 form. 15 A. I'm an occupational medicine 16 physician, and I have a significant amount of 17 awareness and training regarding asbestos as 18 it relates to occupational exposures and 19 general environmental exposures, but I don't 20 consider myself an asbestos expert. 21 BY MR. ZELLERS: 22 Q. What percentage of your time do 23 you spend working as a consultant? And I'm 24 talking about your professional time.</p>	<p>1 A. Yes. 2 Q. What other litigations have you 3 been involved in as an expert? 4 A. Well, I've been asked to 5 provide opinions and testify in a number of 6 cases, most of which involved personal injury 7 in the occupational setting or environmental 8 exposures. 9 Q. Has the majority of your expert 10 work in the occupational setting and for 11 environmental exposures been on behalf of 12 plaintiffs? 13 A. No, it's been split about 14 50/50, plaintiff and defense. 15 Q. Have you ever been retained in 16 a case involving cosmetic products? 17 A. No. 18 Q. Your curriculum vitae that we 19 marked as Exhibit 3, is it correct and up to 20 date? 21 A. It was up to date at the time 22 of submission of my report in the end of 23 2018. 24 Q. What additions need to be made</p>

15 (Pages 54 to 57)

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<p style="text-align: right;">Page 58</p> <p>1 or corrections need to be made to your CV, 2 Exhibit 3, to bring it up to date? 3 A. Well, I've terminated a 4 relationship with the University of Texas 5 Medical Branch in Galveston where I was 6 their -- the medical director of their 7 Employee Health Services Clinic. I continue 8 to be -- serve as an assistant clinical 9 professor of preventive medicine and family 10 medicine at that institution. 11 I have terminated my 12 relationship with the Enbridge Corporation as 13 their medical director. 14 The Spectra Energy entry, which 15 is about the seventh on the list of 16 professional activities, is also terminated 17 as that was a company that was merged and 18 became Enbridge. 19 Q. Any other corrections or 20 updates to your curriculum vitae that we've 21 marked as Exhibit 3? 22 A. No. 23 Q. Why are you no longer serving 24 as medical director, Employee Health Services</p>	<p style="text-align: right;">Page 60</p> <p>1 is that right? 2 A. Yes. 3 Q. What percentage of your time is 4 spent in the clinical practice of medicine? 5 A. Currently I see patients 6 one-half day a week and work as a supervisor 7 of the occupational medicine residents for 8 additional time during the week, so clinical 9 activities would be about probably 12 hours a 10 week. 11 Q. Do you see or treat women for 12 gynecologic cancer? 13 A. I do not. 14 Q. You have never worked for a 15 company that manufactures cosmetic products, 16 correct? 17 A. That's correct. 18 Q. You're not a gynecologist or an 19 oncologist, correct? 20 A. That's correct. 21 Q. You're not a cancer biologist? 22 MS. O'DELL: Object to the 23 form. 24 A. That's correct.</p>
<p style="text-align: right;">Page 59</p> <p>1 with the University of Texas? 2 MS. O'DELL: Objection to form. 3 A. That was a contract that I had 4 through the University of Texas Houston 5 College of Nursing that provided those 6 services to UTMB, and UTMB decided to make a 7 change and go with another contractor. 8 BY MR. ZELLERS: 9 Q. Why are you no longer serving 10 as medical director for Spectra Energy 11 Corporation and Enbridge Corporation? 12 A. Well, Spectra Energy no longer 13 exists; it became Enbridge Corporation. And 14 in October of 2018, I determined that I did 15 not -- I no longer had sufficient time to 16 provide that service. 17 Q. Your undergraduate degree was 18 in biologic sciences with a concentration in 19 engineering; is that right? 20 A. Yes. 21 Q. You received a Ph.D. in 22 toxicology; is that right? 23 A. Yes. 24 Q. And then later an M.D. degree;</p>	<p style="text-align: right;">Page 61</p> <p>1 BY MR. ZELLERS: 2 Q. You are not a geologist, 3 mineralogist or microscopist? 4 A. That's correct. 5 Q. You're not an epidemiologist? 6 A. Well, I may be considered an 7 epidemiologist simply by my appointment as an 8 associate professor in the Department of 9 Epidemiology at the School of Public Health 10 here in Houston. 11 Q. Do you have any professional 12 education in the field -- well, strike that. 13 Have you ever published or 14 conducted a meta-analysis? 15 A. I have conducted meta-analyses. 16 I've not published them. 17 Q. You did not do any type of 18 fellowship in epidemiology, correct? 19 A. That's correct. 20 Q. You're not board certified in 21 epidemiology; is that right? 22 A. I don't believe there is a 23 board certification in epidemiology. 24 Q. You're not a biostatistician or</p>

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<p>1 a pulmonologist?</p> <p>2 A. That's correct.</p> <p>3 Q. You're not a material</p> <p>4 scientist?</p> <p>5 A. That's correct.</p> <p>6 Q. Nor are you a pathologist?</p> <p>7 A. Correct.</p> <p>8 Q. You've never been involved in</p> <p>9 any pathological exam or research relating to</p> <p>10 ovarian cancer; is that right?</p> <p>11 MS. O'DELL: Object to the</p> <p>12 form.</p> <p>13 A. I'm not sure exactly what you</p> <p>14 mean by your question.</p> <p>15 BY MR. ZELLERS:</p> <p>16 Q. Sure. Let me withdraw that.</p> <p>17 You've never been involved in</p> <p>18 terms of the research relating to ovarian</p> <p>19 cancer, correct?</p> <p>20 A. Not specifically, no.</p> <p>21 Q. You've never authored any</p> <p>22 literature or publications relating to talcum</p> <p>23 powder?</p> <p>24 A. No.</p>	<p>1 A. I think I had opinions about</p> <p>2 talcum powder and its constituents, but if</p> <p>3 you could be more specific, I might be able</p> <p>4 to give you a more specific answer.</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. Did you ever, before getting</p> <p>7 involved in this litigation in October of</p> <p>8 2018, do research -- strike that.</p> <p>9 You've never published on</p> <p>10 talcum powder, correct?</p> <p>11 A. That's correct.</p> <p>12 Q. You have never published on the</p> <p>13 constituent components of talcum powder,</p> <p>14 correct?</p> <p>15 A. That may not be the case. I've</p> <p>16 done work in some other minerals which have</p> <p>17 resulted in publications, for example,</p> <p>18 vermiculite, which have touched on the issues</p> <p>19 of asbestos, association with talc,</p> <p>20 association with other minerals, but never</p> <p>21 specifically regarding talc.</p> <p>22 Q. Are those publications on your</p> <p>23 CV?</p> <p>24 A. They are.</p>
Page 63	Page 65
<p>1 Q. Or relating to ovarian cancer,</p> <p>2 correct?</p> <p>3 A. No.</p> <p>4 Q. Okay. What journals -- well,</p> <p>5 strike that.</p> <p>6 You have never published on</p> <p>7 fragrance chemicals; is that right?</p> <p>8 MS. O'DELL: Object to the</p> <p>9 form.</p> <p>10 A. That's correct.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. Never done any research on</p> <p>13 fragrance chemicals, correct?</p> <p>14 A. I've done some work with</p> <p>15 fragrance chemicals and health effects that</p> <p>16 are associated with them, but I have not -- I</p> <p>17 would not classify that as research or</p> <p>18 publication.</p> <p>19 Q. You had no opinions regarding</p> <p>20 talcum powder or any of its constituent</p> <p>21 components before getting involved in this</p> <p>22 litigation; is that right?</p> <p>23 MS. O'DELL: Object to the</p> <p>24 form.</p>	<p>1 Q. That we marked as Exhibit 3?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Have you ever</p> <p>4 communicated with the FDA regarding talcum</p> <p>5 powder?</p> <p>6 A. I've not.</p> <p>7 Q. Have you ever communicated with</p> <p>8 Health Canada regarding talcum powder?</p> <p>9 A. No.</p> <p>10 Q. When did you first start</p> <p>11 preparing your report which we've marked as</p> <p>12 Exhibit 2?</p> <p>13 A. Well, I began a literature</p> <p>14 review immediately after talking to</p> <p>15 Mr. Abney.</p> <p>16 Q. My question, I guess, is: When</p> <p>17 did you start writing your report?</p> <p>18 A. Well, technically I started</p> <p>19 writing my report after I was retained by</p> <p>20 plaintiffs' counsel.</p> <p>21 Q. Late October, early</p> <p>22 November 2018?</p> <p>23 MS. O'DELL: Object to the</p> <p>24 form, misstates his prior testimony.</p>

17 (Pages 62 to 65)

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<p>1 A. In October of 2018. 2 BY MR. ZELLERS: 3 Q. Have you reviewed any of the 4 deposition transcripts of any of the experts 5 that have been deposed in this litigation? 6 A. Yes. 7 Q. What deposition transcripts of 8 experts have you reviewed? 9 A. Oh, of experts? No, I have not 10 reviewed -- well, I've reviewed -- I've 11 reviewed expert depositions, but I don't know 12 what case they were deposed in, but it 13 relates to talcum powder and ovarian cancer 14 issue. 15 Q. What expert depositions have 16 you reviewed? 17 A. They're all cited in the 18 literature exhibit. 19 Q. All of the deposition 20 transcripts that you've reviewed are cited in 21 Exhibit 4? 22 A. I think any of the transcripts 23 that I review are -- reviewed are probably 24 included in here.</p>	<p>1 and bolts of what goes on legally in this 2 case. I know there are multiple lawsuits, 3 and I'm not sure which ones those -- these 4 are pertinent to. 5 BY MR. ZELLERS: 6 Q. My question is a little 7 different and I hope pretty simple: In 8 addition to the depositions, transcripts and 9 reports that you have listed on pages 27 and 10 28 of Exhibit 4, your literature list, are 11 there any additional depositions or 12 transcripts that you've reviewed? 13 A. Pardon me for a moment while I 14 review this. 15 (Document review.) 16 A. No, I'm not aware that there 17 are. 18 BY MR. ZELLERS: 19 Q. Your testimony earlier was that 20 you have reviewed each of those depositions 21 in their entirety; is that right? 22 A. Yes. 23 Q. You have also reviewed the 24 exhibits to those depositions; is that right?</p>
Page 67	Page 69
<p>1 Q. Are you aware of reviewing any 2 transcripts that you did not include in your 3 literature statement? 4 A. I'm not aware, but I can't tell 5 you as I'm sitting here right now whether all 6 of those are included in this literature 7 statement or not. 8 Q. You -- looking at page -- 9 MS. O'DELL: I'm sorry. Go 10 ahead. 11 BY MR. ZELLERS: 12 Q. Are there any that you believe 13 you have reviewed that are not included in 14 the literature statement? 15 A. Well, let me just see here. 16 There are -- 17 MS. O'DELL: I think they're at 18 the end, Dr. Carson. 19 THE WITNESS: At the very end. 20 A. Beginning on page 27 is a list 21 of the depositions, transcripts and reports 22 that I've reviewed, which include some of the 23 expert witnesses, but again, I would have to 24 say I'm -- I'm sort of unaware of the nuts</p>	<p>1 A. If they were made available to 2 me, I've looked at all those exhibits as 3 well. 4 Q. On page 27 of Exhibit 4, who is 5 Annie Yessaian? 6 A. On page 24? 7 Q. Strike that. I'm sorry. On 8 page 27 of Exhibit 4 -- 9 A. I see. 10 Q. -- at the bottom, who is Annie 11 Yessaian? 12 A. I don't recall. 13 Q. You reviewed her entire 14 transcript and you don't recall who she is? 15 A. I don't. 16 Q. Well, go to the next page. Who 17 is Pat Downey? 18 A. I believe Pat Downey is an 19 operative of the Imerys company. 20 Q. Do you know what Mr. Downey's 21 position is? 22 A. It's a supervisory position 23 regarding -- regarding quality of the talc 24 product.</p>

18 (Pages 66 to 69)

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<p>1 Q. Who is John Hopkins?</p> <p>2 A. John Hopkins is an official, I</p> <p>3 believe, of -- I'm not sure -- of Johnson &</p> <p>4 Johnson, I believe, who has some oversight of</p> <p>5 talc quality as well.</p> <p>6 Q. Susan Nicholson, who is she?</p> <p>7 A. I don't recall.</p> <p>8 Q. Who is Julie Pier?</p> <p>9 A. Julie Pier is another scientist</p> <p>10 who works for Imerys, who is responsible for</p> <p>11 testing and quality.</p> <p>12 Q. In your clinical and academic</p> <p>13 practice, do you typically rely upon</p> <p>14 depositions of company witnesses or experts?</p> <p>15 MS. O'DELL: Object to the</p> <p>16 form.</p> <p>17 A. If there's pertinent</p> <p>18 information in there that leads me to other</p> <p>19 areas or helps me formulate my opinions, then</p> <p>20 yes.</p> <p>21 BY MR. ZELLERS:</p> <p>22 Q. In the papers and publications</p> <p>23 that you have identified in your curriculum</p> <p>24 vitae, Exhibit 3, do you ever recall citing</p>	<p>1 BY MR. ZELLERS:</p> <p>2 Q. Once you looked at these</p> <p>3 documents, the Imerys documents and the</p> <p>4 documents produced by the Johnson & Johnson</p> <p>5 companies, did you ask plaintiffs' counsel</p> <p>6 for any additional documents?</p> <p>7 A. I did not. My understanding is</p> <p>8 that most of these are reports, testing</p> <p>9 reports, and most of them are positive</p> <p>10 results regarding the presence of asbestos or</p> <p>11 fibers in the product. And I know that there</p> <p>12 were many others that may not have shown</p> <p>13 positive results that I did not look at.</p> <p>14 Q. Did you ask the plaintiff</p> <p>15 attorneys to show you or provide you with the</p> <p>16 testing documentation that showed an absence</p> <p>17 of asbestos or asbestos fibers in the talcum</p> <p>18 powder?</p> <p>19 A. Regarding the test results that</p> <p>20 are equivalent to these that were negative,</p> <p>21 no, I did not request those.</p> <p>22 Q. Did you review documents</p> <p>23 relating to any fragrance chemicals that are</p> <p>24 contained in or that you believe are</p>
Page 71	Page 73
<p>1 to company witness deposition testimony?</p> <p>2 A. I don't typically cite</p> <p>3 deposition testimonies in published papers.</p> <p>4 Q. You cite to various company</p> <p>5 documents. This is on pages 29 to 30 of</p> <p>6 Exhibit 4, your list of literature; is that</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. Did you rely on these documents</p> <p>10 in formulating your opinions?</p> <p>11 A. Yes.</p> <p>12 Q. Were these documents selected</p> <p>13 for you by plaintiffs' counsel?</p> <p>14 A. Yes, they were.</p> <p>15 Q. Are you able to identify what</p> <p>16 each of the documents are?</p> <p>17 MS. O'DELL: Based on the Bates</p> <p>18 number?</p> <p>19 MR. ZELLERS: Based on the</p> <p>20 Bates numbers.</p> <p>21 A. No, I am not. I would have to</p> <p>22 look at each individual document to refresh</p> <p>23 my memory as to what it contains.</p> <p>24 ///</p>	<p>1 contained in the talcum powder?</p> <p>2 A. Yes. I did review some lists</p> <p>3 and, of course, Dr. Crowley's report.</p> <p>4 Q. Do you have any idea or</p> <p>5 understanding as to the amount or amounts of</p> <p>6 the fragrance chemicals that are contained in</p> <p>7 the talcum powder in either the Johnson &</p> <p>8 Johnson Consumer company talcum powder that's</p> <p>9 involved in this litigation?</p> <p>10 MS. O'DELL: Object to the</p> <p>11 form.</p> <p>12 MR. ZELLERS: Let me withdraw</p> <p>13 that.</p> <p>14 BY MR. ZELLERS:</p> <p>15 Q. Do you know or have any</p> <p>16 understanding as to the amounts of fragrance</p> <p>17 chemicals that are in the talcum powder?</p> <p>18 A. I do not have the specific</p> <p>19 formulation or quantities of those substances</p> <p>20 that contributed to the products.</p> <p>21 Q. Do --</p> <p>22 MS. O'DELL: Excuse me.</p> <p>23 MR. ZELLERS: Ms. O'Dell,</p> <p>24 please, I'm going to let the doctor</p>

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<p>1 finish.</p> <p>2 MS. O'DELL: In that instance,</p> <p>3 I don't know that he was, and so if he</p> <p>4 was, my apologies.</p> <p>5 MR. ZELLERS: It's okay.</p> <p>6 MS. O'DELL: I've been on my</p> <p>7 best behavior today, as you know,</p> <p>8 so -- but I don't want the witness to</p> <p>9 feel as if they're being cut off, and</p> <p>10 because Dr. Carson is a very polite</p> <p>11 gentlemen, he would let you interrupt</p> <p>12 him.</p> <p>13 MR. ZELLERS: Of course.</p> <p>14 MS. O'DELL: And I don't think</p> <p>15 that's fair.</p> <p>16 So, Dr. Carson, if you're</p> <p>17 finished, great. If you're not, you</p> <p>18 may continue.</p> <p>19 A. Well, I was going to say that</p> <p>20 my opinion is that there are very small</p> <p>21 quantities of those substances that</p> <p>22 contribute to the fragrance component.</p> <p>23 BY MR. ZELLERS:</p> <p>24 Q. Do you know how those</p>	<p>1 understanding of business practices and these</p> <p>2 types of industries, I've reviewed an</p> <p>3 extremely small percentage of those.</p> <p>4 Q. Is it your practice in your</p> <p>5 academic work or your clinical research work</p> <p>6 to rely on internal company documents?</p> <p>7 A. Yes, it is.</p> <p>8 Q. Do you rely on internal company</p> <p>9 documents when you publish papers?</p> <p>10 A. In some cases.</p> <p>11 Q. Can you tell me in what cases</p> <p>12 or instances you have relied on internal</p> <p>13 company documents in your publications?</p> <p>14 A. Well, for example, I did -- I</p> <p>15 was involved in some research work in</p> <p>16 conjunction with NIOSH at the O.M. Scott</p> <p>17 Company at Marysville, Ohio, where we did</p> <p>18 a -- we performed a research in the company</p> <p>19 and relied on some internal documents in</p> <p>20 terms of gauging concentrations, industrial</p> <p>21 hygiene records and so forth, in order to</p> <p>22 draw conclusions that were pertinent to those</p> <p>23 publications.</p> <p>24 Q. Was that data or were those</p>
Page 75	Page 77
<p>1 quantities of fragrance chemicals may have</p> <p>2 changed over the years?</p> <p>3 A. My understanding is they have</p> <p>4 not changed dramatically, but there have been</p> <p>5 certain substitutions over time.</p> <p>6 Q. Do you agree that to the extent</p> <p>7 that you have reviewed internal documents,</p> <p>8 either of Imerys or from Johnson & Johnson</p> <p>9 companies, that you have only reviewed the</p> <p>10 documents that were hand-selected by the</p> <p>11 plaintiff lawyers for you to review?</p> <p>12 MS. O'DELL: Object to the</p> <p>13 form.</p> <p>14 A. I agree that the only documents</p> <p>15 that I've reviewed regarding the internal</p> <p>16 products of Johnson & Johnson or Imerys are</p> <p>17 the ones that were provided by the</p> <p>18 plaintiffs' attorneys.</p> <p>19 BY MR. ZELLERS:</p> <p>20 Q. Do you know what percentage of</p> <p>21 the documents that have been produced in this</p> <p>22 litigation by the Johnson & Johnson companies</p> <p>23 and by Imerys you have reviewed?</p> <p>24 A. Well, based on my general</p>	<p>1 internal communications that you relied on?</p> <p>2 A. They were both.</p> <p>3 Q. What is the publication on your</p> <p>4 CV where you relied on those materials?</p> <p>5 A. Well, let me see here. I think</p> <p>6 the first author -- looking back here -- the</p> <p>7 first author would be Jim Lockey.</p> <p>8 Q. Looking at page 6?</p> <p>9 A. It's on page 6, and the --</p> <p>10 there are two publications there. One is</p> <p>11 Pulmonary Changes After Exposure to</p> <p>12 Vermiculite Contaminated With Fibrous</p> <p>13 Tremolite that appeared in the American</p> <p>14 Review of Respiratory Disease in 1984.</p> <p>15 There's another publication</p> <p>16 which is a book chapter called Pulmonary</p> <p>17 Hazards From Vermiculite that appeared in a</p> <p>18 book titled Health Issues Related to Metal</p> <p>19 and Nonmetallic Mining.</p> <p>20 Q. Do you agree that when you have</p> <p>21 been provided only a small subset of the</p> <p>22 documents of a company relating to a</p> <p>23 particular product, that those documents can</p> <p>24 potentially be misleading?</p>

20 (Pages 74 to 77)

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<p>1 MS. O'DELL: Object to the 2 form. 3 A. I don't agree that that's the 4 case because I am capable of understanding 5 that it's a subset of available information, 6 and I can make a reliable determination on 7 the pertinence of that material regardless. 8 BY MR. ZELLERS: 9 Q. Without looking at any other 10 documents or any documents that may put the 11 documents you were provided in context? 12 MS. O'DELL: Object to the 13 form. 14 A. It depends on the specific 15 case, but I would say in most cases, yes. 16 BY MR. ZELLERS: 17 Q. In this case, it was not 18 necessary for you to look at any documents 19 other than those specific documents the 20 plaintiffs provided to you; is that your 21 testimony? 22 MS. O'DELL: Object to the 23 form. 24 A. Regarding the contribution to</p>	<p>1 department? 2 A. She's in my department, yes. 3 Q. You understand she's a 4 lawyer -- strike that. 5 You understand she's an expert 6 for the plaintiffs in this litigation? 7 A. I didn't know that. 8 Q. Dr. Ness never told you that 9 she was an expert witness for plaintiffs in 10 this matter? 11 A. No, we didn't discuss this 12 case. We only discussed the issue. 13 Q. Any other colleagues that you 14 discussed your report and opinions with? 15 MS. O'DELL: Object to the 16 form. 17 A. I think I shared some of my 18 thinking with the occupational medicine 19 residents as a group and asked them to 20 consider certain issues in the case. 21 BY MR. ZELLERS: 22 Q. Did they contribute to your 23 review and analysis and opinions? 24 A. We had an interesting</p>
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<p>1 my opinions, I would say, yes, it was not 2 necessary. 3 BY MR. ZELLERS: 4 Q. Did you do any independent 5 investigation to reach your opinions, other 6 than the literature search and review of 7 websites that you told us about earlier? 8 A. Other than just general 9 discussion with colleagues, no. 10 Q. Did any of the colleagues that 11 you spoke with provide you with any 12 substantive support for your opinions? 13 A. Not that I can recall. It was 14 mostly just helpful feedback. 15 Q. The colleagues that you spoke 16 with were who? 17 A. Various colleagues in my 18 department or in the School of Public Health. 19 Q. Who? 20 A. Well, Dr. George Delclos, who 21 is a pulmonologist; Dr. Brett Perkison, who 22 is an occupational medicine physician; 23 Roberta Ness, who is an epidemiologist. 24 Q. Roberta Ness is in your</p>	<p>1 discussion, but I don't think that changed my 2 opinions in any way. 3 Q. The opinions that you're 4 expressing in this case are your opinions; is 5 that right? 6 A. That's correct. 7 Q. Your opinions you set forth in 8 your report beginning on page 7; is that 9 right? 10 A. Let me refer to my report, if 11 you don't mind. 12 MS. O'DELL: Object to the 13 form. 14 A. I would say -- I would say in 15 answer to that question that, yes, my 16 opinions do begin on page 7 of the report. 17 BY MR. ZELLERS: 18 Q. Your first opinion set forth on 19 page 7 is that talcum powder is immunogenic 20 and carcinogenic; is that right? 21 A. Yes. 22 MS. O'DELL: Excuse me. 23 BY MR. ZELLERS: 24 Q. Your second opinion is that</p>

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<p>1 perineal use of talcum powder results in 2 direct exposure to the ovaries either via 3 inhalation or migration through the female 4 reproductive tract, correct? 5 A. I would not phrase the opinion 6 in that way, but in general, that is my 7 opinion, yes. 8 Q. How would you phrase your 9 second opinion? 10 A. I think my second opinion 11 relates mostly to the direct exposure to the 12 reproductive tract that perineal use of 13 talcum powder produces. 14 Q. Are you opining as to 15 inhalation as an exposure of talcum powder to 16 women's ovaries? 17 MS. O'DELL: Object to the 18 form. 19 A. Only as a secondary route of 20 exposure. 21 BY MR. ZELLERS: 22 Q. Is it part of your opinions or 23 do you defer to other experts on inhalation? 24 A. I would include that as my</p>	<p>1 MS. O'DELL: Object to the 2 form. 3 A. It's an anatomical fact. The 4 physiology of the reproductive system does 5 not provide the ovaries with the kind of 6 clearance system that, for example, the lungs 7 would have for inhaled exposures. 8 BY MR. ZELLERS: 9 Q. The words "no intrinsic 10 elimination system," are those your words or 11 are those words that you've seen reported in 12 another study or another paper? 13 A. I think that's a fairly generic 14 description, that those are my words. 15 Q. Your fourth opinion is that you 16 believe that the epidemiological studies on 17 talcum powder and ovarian cancer show about a 18 30% increased risk; is that right? 19 A. Correct. 20 MS. O'DELL: Object to the 21 form. 22 BY MR. ZELLERS: 23 Q. As you told us at the outset, 24 those are all still your opinions, although</p>
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<p>1 opinion. 2 Q. So you're testifying here today 3 that the perineal use of talcum powder 4 results in direct exposure to the ovaries 5 through migration through the female 6 reproductive tract and that inhalation also 7 results in exposure of talcum powder to the 8 ovaries; is that right? 9 A. That is correct, but my basic 10 opinion is that perineal use of talcum powder 11 exposes the entire reproductive tract, 12 including the pelvic cavity. So it's a bit 13 more extensive than your phrasing. 14 Q. Your third opinion is very 15 similar to your first opinion, except that 16 here you add that it's your opinion that the 17 ovaries are particularly susceptible to the 18 carcinogenicity of talcum powder because they 19 have, in your words, "no intrinsic 20 elimination system"; is that right? 21 A. That's correct. 22 Q. Is that something you came up 23 with on your own, no intrinsic elimination 24 system?</p>	<p>1 you do believe even stronger that there is a 2 causal association between talcum powder and 3 ovarian cancer; is that right? 4 A. That's correct. 5 Q. Have you published on your 6 theory that baby powder causes ovarian 7 cancer? 8 A. No. 9 Q. Do you have plans to do that? 10 A. Not presently. 11 Q. Have you conducted any tests or 12 experiments to confirm your theory that talc 13 migrates to the ovaries? 14 MS. O'DELL: Object to the 15 form. 16 A. These are conclusions that I 17 have drawn based on published literature. I 18 wouldn't characterize them as a theory. I 19 think they're pretty much established fact. 20 BY MR. ZELLERS: 21 Q. I'm going to ask you about all 22 these opinions, and so we'll go through the 23 literature and determine -- or at least I'll 24 ask you questions about why you think that</p>

22 (Pages 82 to 85)

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<p>1 some of these matters are established fact. 2 My question is: Did you do any 3 tests or experiments as part of your review 4 and analysis in this matter? 5 A. I did not. 6 Q. Did you do any tests or 7 experiments relating to your opinion that 8 talc causes cancer via inflammation? 9 A. I did not. 10 Q. Can you identify any article 11 that identifies inflammation anywhere in a 12 woman's reproductive tract that results from 13 external genital talc application? 14 MS. O'DELL: Object to the 15 form. 16 A. I think there are a number of 17 published articles that allude to that 18 relationship and draw a fairly strong 19 conclusion that it exists. 20 MS. O'DELL: Mike, excuse me, 21 and I'm sorry to interrupt. We've 22 been going over an hour and a half. 23 Are you at a point where we can take 24 just a short break for...</p>	<p>1 you aware of any article that identifies 2 inflammation in a woman's reproductive tract 3 resulting from external genital talc 4 application? 5 MS. O'DELL: Object to the 6 form. 7 A. I would say that the studies 8 which have looked at that have relied on the 9 result of internal application to show 10 migration. There have been studies that have 11 shown inflammation as the result of talc, and 12 in my opinion, external application is the 13 same as internal application in the 14 reproductive tract. 15 BY MR. ZELLERS: 16 Q. I don't mean to be 17 argumentative, and I don't want to be, but 18 can you name me an article that identifies 19 inflammation in a woman's reproductive tract 20 resulting from external genital talc 21 application? 22 MS. O'DELL: Objection, asked 23 and answered. 24 A. I can't specifically.</p>
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<p>1 MR. ZELLERS: Sure, we can. 2 Let me just ask these couple of 3 questions, and then we'll take a 4 break. 5 MS. O'DELL: Sure. 6 BY MR. ZELLERS: 7 Q. So please identify for me any 8 articles that you have reviewed that identify 9 inflammation anywhere in a woman's 10 reproductive tract resulting from external 11 genital talc application. 12 MS. O'DELL: Objection to form. 13 A. I think -- I think the research 14 evidence that includes the epidemiology 15 piece, which is limited to external 16 application of talcum powder, has significant 17 enough correspondence with the biological 18 experimentation literature that it allows us 19 to draw those conclusions. 20 BY MR. ZELLERS: 21 Q. I understand you've drawn some 22 conclusions here, and I'm going to ask you 23 about these conclusions. 24 But what my question is: Are</p>	<p>1 MR. ZELLERS: Let's take a 2 break. 3 THE VIDEOGRAPHER: We're off 4 the record, 10:37, end of Tape 1. 5 (Recess taken, 10:37 a.m. to 6 10:55 a.m.) 7 THE VIDEOGRAPHER: We're on the 8 record at 10:55, beginning of Tape 2. 9 BY MR. ZELLERS: 10 Q. Dr. Carson, two of the things 11 that you have reviewed since authoring your 12 report in November of 2018 that you believe 13 support your conclusions in this matter and 14 your opinions in this matter are the draft 15 screening assessment from Health Canada, 16 which we marked as Exhibit 9, and the Taher 17 paper, which has been marked as Exhibit 7; is 18 that right? 19 A. Yes. 20 Q. Have you looked into what other 21 public health authorities, other than 22 Health Canada, have had to say about talc and 23 ovarian cancer? 24 A. Yes, I have.</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 Q. Did you -- strike that. 2 Are you familiar with the 3 Center for Disease Control in the United 4 States? 5 A. Yes. 6 Q. Did you review the CDC and its 7 position on any relationship between talcum 8 powder and ovarian cancer? 9 A. That may have been part of my 10 review, but I don't specifically recall now 11 what the CDC has on that issue. 12 Q. CDC does not list talc or 13 talcum powder as a risk factor for ovarian 14 cancer, correct? 15 A. It's quite possible. 16 Q. Mayo Clinic and a number of 17 medical centers do not list talc as a risk 18 factor for ovarian cancer, correct? 19 A. That may be true. 20 Q. Did you consider, or are you 21 familiar with the National Cancer Institute? 22 A. I am. 23 Q. National Cancer Institute is a 24 leading health authority in the United</p>	<p style="text-align: right;">Page 92</p> <p>1 MR. ZELLERS: I'm asking the 2 doctor a question. 3 MS. O'DELL: Okay. 4 MR. ZELLERS: So -- 5 MS. O'DELL: That's specific 6 language, and if you have specific 7 language that you're reading from the 8 report or you've taken from the 9 report, I would just ask that you show 10 the doctor. 11 MR. ZELLERS: Ms. O'Dell, I 12 have my question. I'm asking my 13 question. The doctor can either 14 answer my question or not answer my 15 question. I'm not reading from a 16 document. I'm reading from my notes. 17 MS. O'DELL: I object to the 18 form of the question. I think it's 19 unfair. 20 MR. ZELLERS: Can you answer 21 that question, Doctor? 22 A. I would agree that that 23 restates the general opinion of the NCI as 24 published, but in order to verify the</p>
<p style="text-align: right;">Page 91</p> <p>1 States; is that right? 2 A. Yes. 3 Q. Particularly in the area of 4 cancer and materials that may or may not be 5 carcinogenic; is that right? 6 A. Well, the National Cancer 7 Institute is responsible for guiding national 8 research policies as it relates to cancers, 9 and that's one of their considerations is 10 substances that may be related to cancer. 11 Q. When you reviewed what the 12 National Cancer Institute has determined with 13 respect to talcum powder and whether or not 14 it is a risk factor for ovarian cancer, what 15 did you find? 16 A. The most recent publication 17 that I viewed discounts the relationship. 18 Q. In fact, the National Cancer 19 Institute has concluded that the weight of 20 the evidence does not support an association 21 between perineal talc exposure and increased 22 risk of ovarian cancer; is that right? 23 MS. O'DELL: Are you reading a 24 quote from the document?</p>	<p style="text-align: right;">Page 93</p> <p>1 specific wording, I would need to look at the 2 document. 3 BY MR. ZELLERS: 4 Q. Why would you rely on 5 Health Canada but not these other public 6 health organizations, including Center for 7 Disease Control and the National Cancer 8 Institute? 9 A. Well, there are a number of 10 reasons. There are lots of public health 11 organizations. Many of them have different 12 interests and different approaches in the way 13 that they address problems. For example, 14 discussing the National Cancer Institute, its 15 primary focus is on research and treatments 16 regarding cancers, not necessarily causes, 17 but it is a funder of basic research in the 18 United States. 19 Health Canada is an 20 organization whose charge is to -- is to 21 synthesize public health-related positions 22 based on evidence and disseminate those to 23 public -- the public through various 24 healthcare organizations or agencies. And</p>

24 (Pages 90 to 93)

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<p>1 for that reason, I think it's important to</p> <p>2 look at the different focus.</p> <p>3 Also, the Health Canada report</p> <p>4 is a more contemporaneous report, which has</p> <p>5 been based on more recent science than has</p> <p>6 been considered either by the NCI or some of</p> <p>7 the other public health organizations.</p> <p>8 Q. The NCI's most recent update to</p> <p>9 its publication was January of 2019; is that</p> <p>10 right?</p> <p>11 MS. O'DELL: Object to the</p> <p>12 form.</p> <p>13 A. It's current in terms of its</p> <p>14 publication. I don't know that it's January</p> <p>15 of '19; it may be. But it's still not based</p> <p>16 on the most recently available literature.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. But Health Canada is; is that</p> <p>19 right?</p> <p>20 A. Health Canada is based on more</p> <p>21 recent literature than the NCI position.</p> <p>22 Q. Health Canada and its</p> <p>23 assessment is based upon the meta-analysis by</p> <p>24 Taher that we've marked as Exhibit 7; is that</p>	<p>1 very beginning of the public comment period,</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. You agree that Health Canada</p> <p>5 can take up to two years to either take</p> <p>6 action or no action at all; is that right?</p> <p>7 A. I don't know that to be the</p> <p>8 case, but it very well could be.</p> <p>9 Q. How did you come to learn of</p> <p>10 the Health Canada risk assessment?</p> <p>11 A. I believe the attorneys let me</p> <p>12 know about it.</p> <p>13 Q. The attorneys for plaintiffs in</p> <p>14 this matter that retained you?</p> <p>15 A. Yes.</p> <p>16 Q. Were you involved in the Health</p> <p>17 Canada risk assessment prior to its</p> <p>18 publication?</p> <p>19 A. No.</p> <p>20 Q. Have you submitted any comments</p> <p>21 to Health Canada?</p> <p>22 A. Not yet.</p> <p>23 Q. Do you intend to submit</p> <p>24 comments to Health Canada?</p>
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<p>1 right?</p> <p>2 A. It is.</p> <p>3 MS. O'DELL: Object to the</p> <p>4 form.</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. You have reviewed that paper</p> <p>7 and you believe it supports and strengthens</p> <p>8 your opinions in this case; is that right?</p> <p>9 A. Yes.</p> <p>10 Q. Does the National Cancer</p> <p>11 Institute review the peer-reviewed literature</p> <p>12 as it relates to risk factors for ovarian</p> <p>13 cancer?</p> <p>14 A. They have a number of</p> <p>15 committees that are set up for that purpose,</p> <p>16 and it is -- it's a committee approach which</p> <p>17 is handled by a committee chairperson. The</p> <p>18 National Cancer Institute itself has some</p> <p>19 oversight of that process, but they defer to</p> <p>20 the committee chairs.</p> <p>21 Q. You understand that the Health</p> <p>22 Canada assessment is a draft; is that right?</p> <p>23 A. Yes.</p> <p>24 Q. You understand that it's at the</p>	<p>1 A. I might.</p> <p>2 Q. What comments do you intend to</p> <p>3 submit to Health Canada?</p> <p>4 A. I haven't formulated them yet.</p> <p>5 Q. Outside of litigation, do you</p> <p>6 generally rely on draft assessments by</p> <p>7 regulatory agencies?</p> <p>8 MS. O'DELL: Object to the</p> <p>9 form.</p> <p>10 A. Yes.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. Are you familiar with the</p> <p>13 precautionary principle?</p> <p>14 A. I am.</p> <p>15 Q. What is the precautionary</p> <p>16 principle?</p> <p>17 A. The precautionary principle</p> <p>18 states that changes should take place in the</p> <p>19 face of a potential hazard until that hazard</p> <p>20 is proved not to exist. It's a general</p> <p>21 precept that's used in the EU, for example,</p> <p>22 and very different from the one that operates</p> <p>23 in this country.</p> <p>24 Q. The principle in this country</p>

25 (Pages 94 to 97)

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<p>1 is that there needs to be scientific evidence 2 in order to take action; is that right? 3 MS. O'DELL: Object to the 4 form. 5 A. Yes, that's correct. 6 BY MR. ZELLERS: 7 Q. The precautionary principle 8 says even before there's full or complete 9 scientific demonstration of cause and effect, 10 it is appropriate to take a precautionary 11 approach; is that right? 12 A. That's right. 13 Q. The Health Canada follows -- 14 strike that. 15 Health Canada follows and has 16 adopted a precautionary approach; is that 17 right? 18 A. Yes. 19 Q. Please review 20 Deposition Exhibit 14. 21 (Carson Deposition Exhibit 14 22 marked.) 23 BY MR. ZELLERS: 24 Q. Deposition Exhibit 14 is the</p>	<p>1 Did I read that correctly? 2 A. You did. 3 Q. Is that your understanding of 4 what a precautionary approach is? 5 A. Yes. In general, the 6 precautionary principle can be restated that 7 an ounce of prevention is worth a pound of 8 cure. 9 Q. Health Canada does not require 10 a finding of causation such as required in 11 litigation matters in this country, the 12 United States; is that right? 13 A. In order to adopt a document 14 that has a significant effect on general 15 public health practices, no, it does not. 16 Q. The Taher paper, that's another 17 paper that you have reviewed since you 18 published your report; is that right? 19 A. Which paper? I'm sorry. 20 Q. This is what we've marked as 21 Exhibit 7. You brought it with you here 22 today? 23 A. Okay. Yes. 24 Q. You've read the Taher 2018</p>
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<p>1 Health Canada Decision-Making Framework for 2 Identifying, Assessing and Managing Health 3 Risk. 4 Do you see that? 5 A. Yes. 6 Q. If you go to page 5 of 7 Exhibit 14 -- 8 MS. O'DELL: Feel free to 9 take -- review the document if you're 10 not familiar with it, Dr. Carson. 11 BY MR. ZELLERS: 12 Q. One of the underlying 13 principles in the Health Canada 14 decision-making framework is use a 15 precautionary approach; is that right? 16 A. That's right. 17 Q. If we go to page 8, Health 18 Canada defines the use of a precautionary 19 approach, and looking at the second sentence: 20 A precautionary approach to decision-making 21 emphasizes the need to take timely and 22 appropriate preventative action, even in the 23 absence of a full scientific demonstration of 24 cause and effect.</p>	<p>1 manuscript; is that right? 2 A. Yes. 3 Q. Where did you obtain that 4 manuscript from? 5 A. This was obtained directly from 6 one of the coauthors on this study to the 7 plaintiffs' attorneys, who passed it along to 8 me. 9 Q. So one of the coauthors on this 10 study gave it to the plaintiffs' counsel, who 11 then gave it to you; is that right? 12 A. That's correct. 13 Q. Who was the author of this 14 publication, Exhibit 7, that provided the 15 paper to plaintiffs' counsel, if you know? 16 A. I don't recall. 17 Q. But one of these authors; is 18 that right? 19 A. It would -- yes. 20 Q. Why did you not include this 21 paper on either your reliance list or your 22 literature list? 23 A. I didn't have it at the time 24 that those were formulated.</p>

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<p>1 Q. Did you have access to the</p> <p>2 appendices and supplemental tables that are</p> <p>3 referred to in the Taher 2018 publication</p> <p>4 which we've marked as Exhibit 7?</p> <p>5 A. The ones that are not in</p> <p>6 this -- in this document or --</p> <p>7 Q. Yes.</p> <p>8 A. Those -- I have not thoroughly</p> <p>9 examined those, but I do have access to them.</p> <p>10 Q. How do you have access to those</p> <p>11 appendices and supplemental tables?</p> <p>12 A. They were also provided to me</p> <p>13 by plaintiffs' counsel.</p> <p>14 Q. Has the Taher publication,</p> <p>15 which we've marked as Exhibit 7, been peer</p> <p>16 reviewed?</p> <p>17 A. It's in the process. This is a</p> <p>18 manuscript that's just been accepted for</p> <p>19 publication, so it has gone through peer</p> <p>20 review.</p> <p>21 Q. It has gone through peer</p> <p>22 review --</p> <p>23 A. That's my understanding.</p> <p>24 Q. -- and Exhibit 7 is the article</p>	<p>1 A. Yes, I have.</p> <p>2 Q. Do you know any of the authors</p> <p>3 of this paper, Exhibit 7?</p> <p>4 A. No, I don't.</p> <p>5 Q. Do you know the source of</p> <p>6 funding for this paper?</p> <p>7 A. I -- I think the sources of</p> <p>8 funding are mentioned in here.</p> <p>9 Q. Other than what's mentioned in</p> <p>10 the paper, Exhibit 7, do you have any</p> <p>11 knowledge as to the sources of funding?</p> <p>12 A. There's a combination of</p> <p>13 sources. In part, this work is funded</p> <p>14 through the plaintiffs' attorneys.</p> <p>15 Q. Have you communicated with any</p> <p>16 of the authors of this paper?</p> <p>17 A. No.</p> <p>18 Q. Do you know the credentials of</p> <p>19 any of the authors of this paper?</p> <p>20 A. I haven't investigated that.</p> <p>21 Q. In your epidemiological work</p> <p>22 outside of litigation, do you rely on</p> <p>23 articles that are funded at least in part by</p> <p>24 plaintiffs' counsel in litigation?</p>
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<p>1 that you believe will be published; is that</p> <p>2 right?</p> <p>3 A. This is a -- this is a working</p> <p>4 manuscript which has gone through at least</p> <p>5 part of the peer-review process. There may</p> <p>6 be minor edits that occur to this, but this</p> <p>7 is substantially the final article.</p> <p>8 Q. How do you know that?</p> <p>9 A. That's the general process of</p> <p>10 submitting publications to peer-reviewed</p> <p>11 article -- journals.</p> <p>12 Q. How do you know -- I'm sorry,</p> <p>13 did you finish?</p> <p>14 A. I'm finished.</p> <p>15 Q. How did you know the status of</p> <p>16 the peer-review process with respect to</p> <p>17 Exhibit 7?</p> <p>18 A. Because it's been accepted for</p> <p>19 publication.</p> <p>20 Q. How do you know that?</p> <p>21 A. That, I was told by the</p> <p>22 plaintiffs' attorneys.</p> <p>23 Q. And you've accepted that; is</p> <p>24 that right?</p>	<p>1 A. If the articles represent good</p> <p>2 science, I don't really pay much attention or</p> <p>3 worry about the funding source.</p> <p>4 Q. Do you know what conflicts of</p> <p>5 interest any of the authors have?</p> <p>6 A. I don't know specifically. I</p> <p>7 can't recall if they're outlined in here.</p> <p>8 But the -- those are also evaluated based on</p> <p>9 the peer-review process.</p> <p>10 Q. Do you know whether some of the</p> <p>11 authors are serving as consultants to</p> <p>12 plaintiffs' counsel in this litigation?</p> <p>13 A. I know that -- no, I don't know</p> <p>14 that. Excuse me, I gave an incorrect answer.</p> <p>15 Q. Sure. Correct it, please.</p> <p>16 A. I mentioned that part of the</p> <p>17 funding for this research came from</p> <p>18 plaintiffs' counsel, and I'm not -- I don't</p> <p>19 know that that's the case. I was thinking of</p> <p>20 another research report when I said that.</p> <p>21 Q. Do you know whether or not, at</p> <p>22 least in part, funding for this paper, the</p> <p>23 Taher paper, came from plaintiffs' counsel?</p> <p>24 A. No, I don't.</p>

27 (Pages 102 to 105)

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<p>1 Q. Taher, this paper, Exhibit 7, 2 concludes that asbestos contamination does 3 not explain ovarian cancer, correct? 4 A. It does come to that general 5 conclusion. 6 Q. That's a different conclusion 7 than you have formulated in this matter; is 8 that right? 9 A. No, it's not. 10 Q. You agree that asbestos 11 contamination does not explain ovarian 12 cancer; is that right? 13 A. It doesn't completely explain 14 ovarian cancer. 15 Q. Does it explain ovarian cancer? 16 MS. O'DELL: Objection, asked 17 and answered. 18 A. I -- I don't believe it 19 completely explains ovarian cancer, no. 20 BY MR. ZELLERS: 21 Q. Turn to page 41 of Exhibit 7. 22 Look at the last three lines of the paper. 23 The authors of the Taher publication state: 24 The similarity of findings between studies</p>	<p>1 factors is consistency; is that right? 2 A. Yes. 3 Q. You, in fact, are opining in 4 this case that there is consistency among the 5 talcum powder ovarian cancer studies and 6 publications; is that right? 7 A. Yes. 8 Q. The authors of the Taher paper 9 disagree with that conclusion; is that right? 10 MS. O'DELL: Object to the 11 form. 12 A. I don't think they disagree 13 with that. 14 BY MR. ZELLERS: 15 Q. Turn to page 25, Table 2. This 16 is, again, something that you have reviewed 17 in preparation for your deposition; is that 18 right? 19 A. Well, I didn't review it in 20 preparation for the deposition, but I've 21 reviewed it recently. 22 Q. At the request of plaintiffs' 23 counsel, correct? 24 A. Yes.</p>
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<p>1 published prior to and after this point 2 suggest asbestos contamination does not 3 explain the positive association between 4 perineal use of talc powder and the risk of 5 ovarian cancer. 6 Did I correctly state their 7 conclusion? 8 A. Well, there was a final clause 9 of the sentence, but yes, you correctly read 10 that. 11 Q. The Taher authors also 12 discussed the lack of consistency among the 13 various talcum powder studies; is that right? 14 MS. O'DELL: Object to the 15 form. 16 A. I'm sorry, could you repeat 17 that question? 18 BY MR. ZELLERS: 19 Q. Sure. 20 You looked at the Bradford Hill 21 factors in formulating your opinion; is that 22 right? 23 A. Yes. 24 Q. One of the Bradford Hill</p>	<p>1 Q. Table 2 is a summary of 2 evidence for each of the Hill criteria of 3 causation as applied to perineal application 4 of talc and ovarian cancer. 5 Do you see that? 6 A. Yes. 7 Q. Under Consistency, they state 8 that 15 out of 30 studies reported positive 9 and significant associations; is that right? 10 A. Yes. 11 Q. 15 out of 30, that's 50%, 12 right? 13 A. Yes. 14 Q. 50% is no better than a coin 15 toss; is that right? 16 MS. O'DELL: Object to the 17 form. 18 A. Well, I would have to also 19 mention that the majority of those 30 studies 20 found positive associations. These are the 21 ones that showed positive associations that 22 rose to the level of statistical 23 significance. 24 ///</p>

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<p>1 BY MR. ZELLERS: 2 Q. If an association is not 3 statistically significant, then it can be due 4 to chance; is that right? 5 A. But if it's due to chance over 6 and over and over again, and you keep getting 7 a positive association, that argues very 8 strongly against the chance as being the only 9 factor. 10 Q. Can you answer my question: A 11 lack of a statistically significant 12 association is consistent with or can be 13 consistent with no risk, correct? 14 MS. O'DELL: Objection to form, 15 asked and answered. 16 A. If you're referring to an 17 individual study, that might be the case; 18 however, when considering the Bradford Hill 19 criterion of consistency, you look at the 20 overall body of the literature and what it 21 tells you. 22 There's an obvious statistical 23 trend toward positive connection between 24 talcum powder perineal application and the</p>	<p>1 studies that have shown a biological gradient 2 at -- especially in relation to some of the 3 subtypes of ovarian cancer. 4 BY MR. ZELLERS: 5 Q. And I'm going to ask you about 6 those questions, but right now I'm just 7 asking you about the Taher paper. 8 A. Well, I'm trying to just 9 completely answer your question. 10 Q. I'm asking you about the Taher 11 paper. You understand? 12 A. Yes. This is all from the 13 Taher paper that I read you. 14 Q. Section 3.3.1 talks about 15 evidence from human studies. That's on 16 page 20; is that right? 17 A. Yes. 18 Q. This section talks about 19 whether or not there is a consistent 20 dose-response found in those studies; is that 21 right? 22 MS. O'DELL: What sentence are 23 you pointing to? 24 MR. ZELLERS: I'm asking the</p>
Page 111	Page 113
<p>1 occurrence of ovarian cancer, and the more 2 evidence that mounts, the more strongly that 3 association is proven. 4 BY MR. ZELLERS: 5 Q. Would you say that 15 out of 30 6 means there are consistent results across 7 studies? 8 A. I think I've just explained to 9 you how I believe there are consistent 10 results across studies. 11 Q. The authors of the Taher paper 12 also conclude that they do not find a 13 consistent dose-response in the papers that 14 look at perineal application of talc and 15 ovarian cancer; is that right? 16 MS. O'DELL: Object to the 17 form. 18 A. Well, what they actually say is 19 that about half of the epidemiological 20 studies assess only one level of talc 21 exposure, ever versus never. So it's not 22 possible from those studies to establish a 23 biological gradient. 24 However, there are a number of</p>	<p>1 doctor questions based upon his review 2 of the paper, Ms. O'Dell. 3 MS. O'DELL: Okay. Feel free 4 to review it, Doctor, if you need to. 5 THE WITNESS: I'm just taking a 6 look at this section. 7 BY MR. ZELLERS: 8 Q. And if it helps you, look on 9 page 21, lines 174 through 177. 10 (Document review.) 11 BY MR. ZELLERS: 12 Q. I only want to ask you about 13 two sentences. Are you ready for me to ask 14 you my question? 15 A. Just one moment, please. 16 Q. Sure. 17 (Document review.) 18 THE WITNESS: All right, I'm 19 ready for your question. 20 BY MR. ZELLERS: 21 Q. The Taher paper states that 22 many of the studies only reported on the 23 ovarian cancer risk assessing one exposure 24 category and that exposure response analyses</p>

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<p>1 were not done in all studies; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. When conducted, findings from</p> <p>4 trend analyses were not consistent; is that</p> <p>5 correct?</p> <p>6 MS. O'DELL: Object to the</p> <p>7 form.</p> <p>8 A. Yes.</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. All right. With respect -- I'm</p> <p>11 done with that paper.</p> <p>12 You discuss your opinion</p> <p>13 number 1 on page 7 of your report; is that</p> <p>14 right?</p> <p>15 A. Yes.</p> <p>16 Q. You first state on page 7 that</p> <p>17 you believe talcum powder is immunogenic and</p> <p>18 produces chronic inflammation in the tissues;</p> <p>19 is that right?</p> <p>20 A. Yes.</p> <p>21 Q. You state that other components</p> <p>22 in talcum powder, including mineral fibers,</p> <p>23 asbestos, fibrous talc, carcinogenic metals</p> <p>24 and other chemicals intensify the</p>	<p>1 inflammation in the tissues in which it</p> <p>2 sequesters; is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Assuming for the moment that</p> <p>5 talc can reach the ovaries, is it your</p> <p>6 opinion that talc produces chronic</p> <p>7 inflammation in the ovaries and that this</p> <p>8 somehow leads to ovarian cancer?</p> <p>9 A. It is my opinion that talc</p> <p>10 produces chronic inflammation in the</p> <p>11 epithelial tissues of the ovaries and</p> <p>12 surrounding epithelial tissues and leads to</p> <p>13 both carcinogenesis initiation and promotion.</p> <p>14 Q. There are no reports in the</p> <p>15 literature of externally applied talc leading</p> <p>16 to inflammation, granulomas, fibrosis or</p> <p>17 adhesions anywhere along a woman's</p> <p>18 reproductive tract, correct?</p> <p>19 MS. O'DELL: Object to the</p> <p>20 form, asked and answered.</p> <p>21 A. Well, that's similar to the</p> <p>22 question that you asked earlier, and although</p> <p>23 I'm not aware of experimental reports that</p> <p>24 specifically jive with that condition,</p>
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<p>1 inflammatory response and stimulate cell</p> <p>2 growth and proliferation; is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Other than asbestos, what</p> <p>5 mineral fibers in talc intensify the</p> <p>6 inflammatory response?</p> <p>7 A. Well, the endogenous fibrous</p> <p>8 talc fibers also intensify the response.</p> <p>9 Q. Other than asbestos and fibrous</p> <p>10 talc fibers, what mineral fibers in talc do</p> <p>11 you believe intensify the inflammatory</p> <p>12 response?</p> <p>13 A. I'm not really able to answer</p> <p>14 that question because I don't have a specific</p> <p>15 opinion about it. I'm not a geologist.</p> <p>16 Q. Are the other chemicals that</p> <p>17 you refer to in this section fragrance</p> <p>18 chemicals?</p> <p>19 A. Yes.</p> <p>20 Q. Any others?</p> <p>21 A. None that are intentionally</p> <p>22 added.</p> <p>23 Q. You claim, again on page 7,</p> <p>24 that talcum powder produces chronic</p>	<p>1 certainly there are a lot of theoretical</p> <p>2 reports that have been published.</p> <p>3 For example, Dr. Ness' article</p> <p>4 from '99 lays out the theory of inflammation</p> <p>5 and relates that to talc exposure from</p> <p>6 perineal application.</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. This is your colleague,</p> <p>9 Dr. Ness; is that right?</p> <p>10 A. Ness, and Coussens, when she</p> <p>11 was at Pittsburgh.</p> <p>12 Q. Dr. Ness, you showed her your</p> <p>13 report and asked for her comments; is that</p> <p>14 right?</p> <p>15 A. I didn't show her the report.</p> <p>16 Q. Well, you talked to her about</p> <p>17 and showed her your conclusions and your</p> <p>18 opinions; is that right?</p> <p>19 A. No, I talked to her about the</p> <p>20 paper.</p> <p>21 Q. Her paper?</p> <p>22 A. Yes.</p> <p>23 Q. Did you share with her that you</p> <p>24 were going to be an expert for the plaintiffs</p>

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<p>1 in this litigation?</p> <p>2 A. No, I didn't.</p> <p>3 Q. Did she wonder or ask why it</p> <p>4 was that you were researching or looking into</p> <p>5 this issue?</p> <p>6 A. She -- I think she may have,</p> <p>7 yeah.</p> <p>8 Q. And what did you tell her?</p> <p>9 A. I told her I had been recently</p> <p>10 asked to look into it.</p> <p>11 Q. Did you tell her that you'd</p> <p>12 been asked to look into it by counsel for</p> <p>13 plaintiffs in the talc litigation?</p> <p>14 A. No, I didn't.</p> <p>15 Q. And that never came up; is that</p> <p>16 right?</p> <p>17 A. It didn't.</p> <p>18 Q. And she never talked to you or</p> <p>19 told you about her experience and her work as</p> <p>20 counsel -- strike that, as an expert for</p> <p>21 plaintiffs; is that your testimony?</p> <p>22 A. Yes. It was a very brief</p> <p>23 conversation.</p> <p>24 Q. If up to 50% of all U.S. women</p>	<p>1 talc relating to that, and to my knowledge,</p> <p>2 there are no experimental reports or case</p> <p>3 reports that can document that at the current</p> <p>4 time.</p> <p>5 Q. Granulomas, fibrosis and</p> <p>6 adhesions do not cause ovarian cancer,</p> <p>7 correct?</p> <p>8 MS. O'DELL: Object to the</p> <p>9 form.</p> <p>10 A. The inflammatory process that</p> <p>11 is intimately connected with granuloma</p> <p>12 formation may well be the same process that</p> <p>13 results in mutation and promotion of ovarian</p> <p>14 cancer. So I -- I could not agree completely</p> <p>15 with your statement.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. Is there a good scientific</p> <p>18 basis today to opine that granulomas,</p> <p>19 fibrosis or adhesions cause ovarian cancer?</p> <p>20 MS. O'DELL: Object to the</p> <p>21 form.</p> <p>22 A. No, I don't think they cause</p> <p>23 ovarian cancer.</p> <p>24 ///</p>
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<p>1 have used genital talc, shouldn't there be</p> <p>2 studies which have shown inflammation,</p> <p>3 granulomas, fibrosis or adhesions in a</p> <p>4 woman's reproductive tract?</p> <p>5 MS. O'DELL: Object to the</p> <p>6 form.</p> <p>7 A. Well, there are studies that</p> <p>8 show those things.</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. Please, tell me the published</p> <p>11 studies that demonstrate inflammation,</p> <p>12 granulomas, fibrosis or adhesions in a</p> <p>13 woman's reproductive tract from externally</p> <p>14 applied talc?</p> <p>15 A. Well, you're adding a new</p> <p>16 condition now.</p> <p>17 Q. I'm sorry if I didn't add that</p> <p>18 before.</p> <p>19 A. There are multiple studies that</p> <p>20 show inflammation and other inflammatory</p> <p>21 reactions in connection with the occurrence</p> <p>22 of ovarian cancer.</p> <p>23 The piece that you're now</p> <p>24 asking for is the external application of</p>	<p>1 BY MR. ZELLERS:</p> <p>2 Q. Would you agree that not all</p> <p>3 inflammatory conditions lead to cancer?</p> <p>4 A. Yes.</p> <p>5 Q. It's true that all of us</p> <p>6 experience inflammatory reactions of one sort</p> <p>7 or another, including chronic conditions,</p> <p>8 that do not lead to cancer, correct?</p> <p>9 A. That's correct. Although there</p> <p>10 is a strong relationship between inflammatory</p> <p>11 processes and the occurrence of cancers, and</p> <p>12 some of those inflammatory diseases that</p> <p>13 you're referring to also have associations</p> <p>14 with increased rates of cancers.</p> <p>15 MR. ZELLERS: Move to strike as</p> <p>16 nonresponsive.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. Rheumatoid arthritis is an</p> <p>19 inflammatory condition; is that right?</p> <p>20 A. Yes, it is.</p> <p>21 Q. Does it increase the risk of</p> <p>22 ovarian cancer?</p> <p>23 A. I think I -- it does -- it's</p> <p>24 not associated with ovarian cancer, but I</p>

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<p style="text-align: right;">Page 122</p> <p>1 think it may be associated with other 2 cancers. 3 Q. Does -- strike that. 4 Is psoriasis an inflammatory 5 condition? 6 A. Generally, it is. 7 Q. Is it associated with an 8 increased risk of ovarian cancer? 9 A. Not that I'm aware. 10 Q. In your report you state that 11 inflammation is a normal body process that 12 leads to the thwarting of infection and rapid 13 healing; is that right? 14 A. That's correct. 15 Q. If your inflammation theory is 16 correct, why doesn't inflammation generally, 17 such as in pelvic inflammatory disease, cause 18 ovarian cancer? 19 A. It may do so. 20 Q. You are opining under oath here 21 that pelvic inflammatory disease causes 22 ovarian cancer? 23 A. I think there are experts who 24 have concluded that.</p>	<p style="text-align: right;">Page 124</p> <p>1 A. This is a list that I've put 2 together of some of the studies I've 3 considered and how they relate to things I 4 might testify to today. 5 Q. Why did you not tell me about 6 your list that you brought with you today 7 before now? 8 A. Well, I'm telling you about it 9 now. 10 Q. My question is why did you not, 11 when I asked you what you brought to the 12 deposition today, not take the list out and 13 show us the list? 14 A. I didn't think of it. 15 Q. Okay. We'll mark your list as 16 Deposition Exhibit 15. 17 (Carson Deposition Exhibit 15 18 marked.) 19 BY MR. ZELLERS: 20 Q. These are a number of notes, 21 four pages of notes. Are these all your 22 notes? 23 A. Yes. 24 Q. First page has got a section of</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. What study are you relying on 2 for that opinion or statement? 3 A. That's not part of the opinions 4 that I've been asked to consider in this -- 5 in this case. 6 Q. As you sit here, can you cite 7 me a publication or a study that finds that 8 pelvic inflammatory disease causes ovarian 9 cancer? 10 MS. O'DELL: Object to the 11 form. 12 A. Well, I have -- I have a list 13 of studies that relate inflammation to 14 ovarian cancer and other cancers. 15 BY MR. ZELLERS: 16 Q. Can you name me a study or a 17 publication? 18 A. Okay. I think I have my list 19 here. 20 Q. You brought other materials 21 with you? 22 A. I brought this list. 23 Q. All right. Well, what list are 24 you pulling out of your pocket?</p>	<p style="text-align: right;">Page 125</p> <p>1 articles on asbestos and ovarian cancer; is 2 that right? 3 A. Yes. 4 Q. It also has inflammation and 5 cancer and a number of studies; is that 6 right? 7 A. Yes. 8 Q. Second page has got cohort, 9 where you've listed out the four cohort 10 studies; is that right? 11 A. Yes. 12 Q. Beneath that are the 13 meta-analyses where you've listed those out 14 and made some notes on those, correct? 15 A. Yes. 16 Q. The back page of the second 17 page has got a listing of a number of the 18 case-control studies, correct? 19 A. Yes. Those are duplicated on 20 another page. 21 Q. The third page has got a 22 section on migration and studies that you're 23 looking at for that proposition, correct? 24 A. Correct.</p>

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<p style="text-align: right;">Page 126</p> <p>1 Q. Underneath that, ovarian cancer 2 risk; is that right? 3 A. Yes. 4 Q. Underneath that, talc and other 5 cancer; is that right? 6 A. Yes. 7 Q. And then on the last page, 8 page 4, is a listing of the case-control 9 studies with the odds ratios and confidence 10 intervals; is that right? 11 A. For the most part, yes. 12 Q. All right. So looking now at 13 your list of studies that you have prepared, 14 which study demonstrates or supports the 15 proposition that pelvic inflammatory disease 16 causes ovarian cancer? 17 A. Looking through here, I don't 18 have that item specifically in my notes, but 19 I'm just using my notes to refresh my memory 20 about the individual research report. I 21 think the Coussens and Werb paper from 2010 22 talks about general mechanisms of 23 inflammation in relation to the occurrence of 24 ovarian cancer.</p>	<p style="text-align: right;">Page 128</p> <p>1 authors conclude that pelvic inflammatory 2 disease causes ovarian cancer? Do you 3 believe each of the authors in the studies 4 that you've identified, that their studies 5 stand for that proposition? 6 MS. O'DELL: Object to form, 7 asked and answered. 8 A. I think all of the studies that 9 I've identified for this question do allude 10 to that, yes. 11 BY MR. ZELLERS: 12 Q. That pelvic inflammatory 13 disease causes ovarian cancer, correct? 14 A. That it is a -- it's a factor, 15 yes. 16 Q. It's a cause. That's what they 17 state in those papers, right? 18 MS. O'DELL: Object to the 19 form. 20 BY MR. ZELLERS: 21 Q. That's your testimony? 22 MS. O'DELL: Excuse me, 23 misstates his testimony. Object to 24 the form.</p>
<p style="text-align: right;">Page 127</p> <p>1 And there's the Ness and 2 Cottreau paper from '99. 3 Okada has discussed it in the 4 2007 paper. And there's a paper from 2001 5 which is Balkwill and Mantovani which 6 discusses the relationship between talc and 7 ovarian cancer and also discusses the 8 relationship to other sources of 9 inflammation. 10 Q. Each of those papers that 11 you've identified you believe state that 12 pelvic inflammatory disease is a cause of 13 ovarian cancer, correct? 14 MS. O'DELL: Object to the 15 form. 16 A. Well, I don't think they state 17 that in so many words, but if you read the 18 paper and you understand that -- what pelvic 19 inflammatory disease is and its relationship 20 to inflammatory processes in general, yes, 21 that's what they're saying. 22 BY MR. ZELLERS: 23 Q. Doctor, my question to you was: 24 Are you aware of any papers in which the</p>	<p style="text-align: right;">Page 129</p> <p>1 A. I would say it's a factor and 2 leave it at that. 3 BY MR. ZELLERS: 4 Q. All right. Are you familiar 5 with pleurodesis? 6 A. I am. 7 Q. Does a pleurodesis cause 8 cancer? 9 A. It is not known to, although it 10 might. 11 Q. Are you familiar with the 12 study, 1979, A survey of the long-term 13 effects of talc and kaolin pleurodesis? 14 A. Can tell me who the author of 15 that was? 16 Q. Sure. The author is -- this is 17 from the Research Committee of the British 18 Thoracic Association. The members of the 19 subcommittee were Chappell, Johnson, Charles, 20 Wagner, Seal, Berry and Nicholson. 21 Are you familiar with that 22 paper? 23 A. I'm not familiar with the 24 paper. I may have looked at it in the past.</p>

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<p>1 Q. We'll take a look at it. We'll 2 mark it as Deposition Exhibit 16. 3 (Carson Deposition Exhibit 16 4 marked.) 5 A. Thank you. 6 MS. O'DELL: Thank you. 7 BY MR. ZELLERS: 8 Q. This was a study that looked at 9 the association between pleurodesis and lung 10 cancer; is that right? 11 A. Yes. 12 Q. It's a study that you cite on 13 page 1 of your literature list; is that 14 right? 15 A. Okay. Yes. 16 Q. So you've read it; is that 17 right? 18 A. I have. 19 Q. You've considered it; is that 20 right? 21 A. Yes. 22 Q. They looked at 210 patients 23 that underwent a pleurodesis with talc or 24 kaolin 14 to 40 years before; is that right?</p>	<p>1 form. 2 A. I think that was the hypothesis 3 of those research reports. 4 BY MR. ZELLERS: 5 Q. And, in fact, the NSAID studies 6 do not find a consistent causal reduction in 7 the risk of ovarian cancer; is that right? 8 A. I think that's correct. 9 Q. In your report you also state 10 that studies show that use of cornstarch 11 instead of talcum powder reduces the risk of 12 ovarian cancer; is that right? 13 A. Yes. 14 Q. If inflammation causes cancer, 15 why would cornstarch be a superior 16 alternative to talc? 17 A. The reason is that cornstarch, 18 being a biological product, is much -- it 19 does have a rapid clearance from the body, 20 even when sequestered, in comparison with a 21 mineral substance like talc. 22 Q. Well, in fact, cornstarch 23 causes or increases the risk of inflammation, 24 granulomas, fibrosis and adhesions, correct?</p>
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<p>1 A. That's correct. 2 Q. And they found that there was 3 no increased incidence of lung cancer and no 4 cases of mesothelioma; is that right? 5 A. That's correct. 6 Q. Why don't -- well, strike that. 7 You're aware of the studies 8 that have looked at antiinflammatory drugs 9 and aspirin use with respect to whether or 10 not they're associated with -- let me 11 withdraw that. 12 Are you familiar with the NSAID 13 and aspirin use studies relating to the 14 incidence of ovarian cancer in chronic users? 15 A. I'm familiar with some of 16 those, yes. 17 Q. If your theory is correct that 18 inflammation causes ovarian cancer, then you 19 would expect that the studies of NSAIDs and 20 aspirin use, antiinflammatory drugs that 21 reduce inflammation, would consistently 22 reduce the incidence of ovarian cancer, 23 correct? 24 MS. O'DELL: Object to the</p>	<p>1 A. It may, yes. 2 Q. Just like you claim talcum 3 powder increases the risk of inflammation, 4 granulomas, fibrosis and adhesions; is that 5 right? 6 MS. O'DELL: Object to the 7 form. 8 A. I think you are -- you're 9 parsing terms here. That list of things were 10 your words. I was agreeing with the 11 relationship between talc and inflammation in 12 ovarian epithelial tissue and the production 13 or granulomas. I did not discuss the 14 relationship between talc and adhesions or 15 fibrosis. There was one other thing on your 16 list. 17 BY MR. ZELLERS: 18 Q. Well, in fact, the FDA has 19 banned the use of cornstarch as a powder for 20 lubricating surgical gloves; is that right? 21 A. It has, but that's not the 22 reason. 23 Q. Well, the reason that they 24 banned the use of cornstarch is because it</p>

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<p>1 presented an unreasonable and substantial 2 risk of illness or injury and that that risk 3 cannot be corrected or eliminated by 4 labeling, correct? 5 A. I don't know the specific 6 language. It looks like you're reading from 7 a Federal Register document. 8 The main reason that cornstarch 9 has been banned as a lubricant in gloves is 10 because of the potential for transmission of 11 primarily respiratory problems through 12 inhalation, mostly by co-workers, not by 13 patients. 14 Q. You do agree that cornstarch 15 has been banned by the FDA for use in 16 surgical gloves; is that right? 17 A. All powdered gloves have been 18 essentially banned from hospitals and 19 operating rooms now. 20 Q. You also talk about 21 inflammation and oxidative stress; is that 22 right? 23 A. Yes. 24 Q. Does the presence of oxidative</p>	<p>1 Q. Why do you have to have a 2 special definition of "oxidative stress"? 3 I'm asking simply: Is there a publication or 4 a study which documents that oxidative stress 5 is involved in the development of ovarian 6 cancer? 7 MS. O'DELL: Object to the 8 form. 9 A. Sure. 10 BY MR. ZELLERS: 11 Q. And what paper are you going to 12 point me to? 13 A. Well, I'll point you to the 14 Ness paper to begin with, because it was one 15 of the earlier papers that related oxidative 16 stress from talc to the occurrence of ovarian 17 cancer. But the relationship between 18 inflammation, which essentially is the source 19 of the oxidative stress, and cancer goes all 20 the way back into the 19th Century in terms 21 of its proposal as a rationale. 22 Q. Is oxidative stress a variation 23 of inflammation as you're using that term 24 relating to a potential cause of ovarian</p>
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<p>1 stress in a tissue indicate that cancer will 2 develop in that tissue? 3 A. No. 4 Q. If exposure to a substance 5 causes oxidative stress in certain tissue, 6 does that mean exposure of all other tissues 7 to that substance will cause oxidative stress 8 in those tissues? 9 A. Not necessarily. 10 Q. Does the body have protective 11 mechanisms that can limit tissue damage from 12 oxidative stress? 13 A. Yes. 14 Q. Do all substances that cause 15 oxidative stress also cause cancer? 16 A. I'm not sure the answer to that 17 question is known. 18 Q. Are there any studies or 19 publications that indicate that oxidative 20 stress is involved in the development of 21 ovarian cancer? 22 A. If I can define the term 23 "oxidative stress," I could give you an 24 answer to that, that question.</p>	<p>1 cancer? 2 A. It's a component of 3 inflammation. 4 Q. As a toxicologist, how would 5 you define fibrous talc? 6 A. Fibrous talc is a form of talc 7 that is conformed into elongated structures 8 that have an aspect ratio of length greater 9 than width that is different from the 10 majority of talc which is the platy form. 11 Q. Do you consider yourself to be 12 an expert on fibrous talc? 13 A. No, I don't. 14 Q. Do you consider yourself to be 15 an expert on oxidative stress? 16 A. I have dealt a lot with issues 17 of oxidative stress and health effects 18 resulting from it. 19 Q. Do you consider yourself to be 20 an expert in oxidative stress? 21 MS. O'DELL: Objection, asked 22 and answered. 23 A. I'm not a specific expert in 24 oxidative stress, but I can -- I can opine</p>

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<p>1 regarding my professional understanding and 2 training. 3 BY MR. ZELLERS: 4 Q. You've never been involved in 5 terms of any research or publication on the 6 subject of oxidative stress and any 7 association with ovarian cancer, correct? 8 A. Not in terms of ovarian cancer, 9 no. 10 Q. You have not been involved in 11 any research or publication relating to the 12 subject of inflammation and its association 13 with ovarian cancer, correct? 14 A. No. All right. Yes, correct. 15 Q. Yes, it is correct? Okay. 16 You claim that the presence of 17 asbestos and fibrous talc further intensifies 18 the carcinogenic effect of talc; is that 19 right? 20 A. Yes. 21 Q. Is that statement different 22 from the statement directly above where you 23 allege that asbestos and mineral fibers 24 intensify the inflammatory response and</p>	<p>1 reports, the epidemiology first, is looking 2 at the relationship between perineal use of 3 dusting powders, talcum powders and ovarian 4 cancer. 5 Although there have been 6 efforts in some of those studies to 7 characterize the proportion or the 8 ingredients that would be either asbestos or 9 fibers, that's not done in all cases, and 10 it's not ruled out in any cases. 11 The -- also, the research 12 studies that have been performed, the 13 testing, for example, of the products 14 themselves are replete with reports of 15 components of these powders that are fibrous 16 in nature. 17 MR. ZELLERS: Move to strike as 18 nonresponsive. 19 BY MR. ZELLERS: 20 Q. Do you believe that all talcum 21 powder products that are on the market 22 contain asbestos? 23 MS. O'DELL: Object to the 24 form.</p>
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<p>1 stimulate the cell growth and proliferation? 2 A. It's not different, no. 3 Q. Are your opinions dependent on 4 talc containing carcinogenic asbestos and/or 5 fibrous talc? 6 A. No. 7 Q. Do you believe that talcum 8 powder without asbestos causes ovarian 9 cancer? 10 A. I believe talcum powder causes 11 ovarian cancer. I have not seen any research 12 done on talcum powder that has been shown not 13 to contain asbestos. 14 Q. Your assumption that you have 15 made in formulating your opinions here is 16 that talcum powder contains asbestos; is that 17 right? 18 A. No. 19 Q. What assumption have you made 20 as to whether or not talcum powder contains 21 either asbestos or fibrous talc? 22 MS. O'DELL: Object to the 23 form. 24 A. Looking at the research</p>	<p>1 A. I don't know. 2 BY MR. ZELLERS: 3 Q. Does it matter to your opinion 4 as to whether or not the talcum powder 5 products, and particularly the talcum powder 6 products involved in this case, contain 7 asbestos? 8 A. I wouldn't have a way to be 9 able to answer that yes or no. 10 Q. Do you -- strike that. 11 Have you reached a conclusion 12 as to whether or not the talcum powder 13 products involved in this case contain 14 fibrous talc? 15 A. I think that most of them do. 16 Q. Does all of the talcum powder 17 contain fibrous talc or just some of it? 18 A. Certainly a lot of it does. 19 Q. The basis for your conclusion 20 that the talcum powder at issue in this case 21 contains fibrous talc is the testing reports 22 that plaintiffs' attorneys gave you? 23 MS. O'DELL: Object to the 24 form.</p>

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<p style="text-align: right;">Page 142</p> <p>1 A. Yes. Also Longo's publications 2 and reports. 3 BY MR. ZELLERS: 4 Q. You have reviewed the Longo 5 reports; is that right? 6 A. Yes. 7 Q. Have you ever met with him? 8 A. No. 9 Q. Do you know his qualifications? 10 A. I looked at his qualifications 11 at one point, but I don't recall exactly what 12 it is at this stage. 13 Q. Ever hear of him before this 14 lawsuit, your getting involved in the talc 15 litigation back in October of 2018? 16 A. No. 17 Q. Have you reviewed any of 18 Longo's testing where he did not find 19 asbestos? 20 A. I -- the only thing I've 21 reviewed are what's present in those reports 22 that I cited. 23 Q. Were you provided by counsel 24 for plaintiffs with any testing reports from</p>	<p style="text-align: right;">Page 144</p> <p>1 MS. O'DELL: Object to the 2 form. 3 A. That wasn't my charge. I defer 4 to the other experts in this case. 5 BY MR. ZELLERS: 6 Q. Do you have an opinion on what 7 type of asbestos you believe is in the talcum 8 powder products at issue in this case? 9 A. Well, there have been various 10 types shown, but I think for the most part 11 it's tremolite and anthophyllite. 12 Q. Are you familiar with 13 crocidolite? 14 A. Yes. 15 Q. Is crocidolite found in talcum 16 powder or baby powder? 17 A. It's not commonly found in it. 18 Q. You believe that the 19 asbestos -- types of asbestos that may be in 20 the talcum powder at issue in this case is 21 tremolite and acidolite [sic]? 22 MS. O'DELL: Objection. 23 A. Anthophyllite. There are 24 others found, but you asked for most common.</p>
<p style="text-align: right;">Page 143</p> <p>1 Longo where he did not find asbestos? 2 A. There are some of those listed 3 in his reports. 4 Q. Have you reviewed the FDA's 5 testing of talcum powder products? 6 A. The FDA didn't really do much 7 testing of talcum powder products. 8 Q. Have you reviewed the FDA's 9 testing of talcum powder products? 10 MS. O'DELL: Objection, vague. 11 A. The only FDA testing that I 12 looked at was the -- I have it referenced in 13 my list, but the FDA, based on a 14 recommendation, requested samples from 15 various companies, I think nine different 16 sources of talc. They received four and 17 tested those. And based on their test method 18 determined that there was not a -- not 19 evidence of a significant hazard. 20 BY MR. ZELLERS: 21 Q. Have you made any effort to 22 quantify the amount of any alleged 23 contaminant in the Johnson & Johnson Consumer 24 talcum powder?</p>	<p style="text-align: right;">Page 145</p> <p>1 BY MR. ZELLERS: 2 Q. Most common you believe are 3 tremolite and anthophyllite? 4 A. Anthophyllite. 5 Q. Anthophyllite. Those two; is 6 that right? 7 A. Yes. 8 Q. What types of asbestos are 9 associated with ovarian cancer? 10 A. Well, I'll go back to my list 11 again. Crocidolite is associated with 12 ovarian cancer in the Acheson report from 13 1982, which was from female gas mask 14 manufacturers in England who made gas masks 15 during the period of the Second World War, 16 and crocidolite is associated with that with 17 a fairly high relative risk of 2.96. 18 Chrysotile asbestos had also a positive 19 relative risk of 1.74. 20 There was a study of factory 21 workers and pipe laggers in east London, 22 which is the Berry report from 2000, that 23 showed a relative risk of 2.53, and those 24 workers were exposed to primarily asbestos</p>

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<p style="text-align: right;">Page 146</p> <p>1 cement products and plasters, so the --</p> <p>2 Q. What type of asbestos, if you</p> <p>3 know?</p> <p>4 A. That would have been primarily</p> <p>5 amphibole asbestos types, which would include</p> <p>6 crocidolite and tremolite and anthophyllite,</p> <p>7 amosite is in that category.</p> <p>8 Bertolotti in 2008 published a</p> <p>9 report -- actually, there were several</p> <p>10 reports that resulted from the Eternit</p> <p>11 factory studies in Casale Monferrato in</p> <p>12 Italy, which was a plant that manufactured</p> <p>13 cement sheet and corrugated tubing, and there</p> <p>14 were a number of studies that showed elevated</p> <p>15 relative risks in persons exposed to asbestos</p> <p>16 in that work, and that would also have been</p> <p>17 amphibole asbestos types.</p> <p>18 Q. The studies that you've recited</p> <p>19 for us, those are all occupational studies;</p> <p>20 is that right?</p> <p>21 A. Yes. I've got a lot more.</p> <p>22 Q. Well, and it's on your list,</p> <p>23 which we marked as Exhibit 15; is that right?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 148</p> <p>1 But based on my current</p> <p>2 understanding, I don't believe they've ever</p> <p>3 been totally successful in doing so.</p> <p>4 So in answer to your question,</p> <p>5 which I think was, was there ever a point in</p> <p>6 time where you believe the talcum powder</p> <p>7 products involved in this case were not</p> <p>8 contaminated with asbestos, no.</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. You cite in your report,</p> <p>11 page 5, to two exhibits to the depositions of</p> <p>12 John Hopkins and Julie Pier in support of</p> <p>13 your opinion that talcum powder products</p> <p>14 contain asbestos; is that right?</p> <p>15 A. That's correct.</p> <p>16 Q. Looking at page 5, footnote 1,</p> <p>17 you cite to Exhibit Hopkins-28 in the Hopkins</p> <p>18 deposition and Exhibit Pier-47 in the Pier</p> <p>19 deposition; is that right?</p> <p>20 A. That's correct.</p> <p>21 Q. Are you aware that those</p> <p>22 exhibits were created by plaintiffs' counsel?</p> <p>23 MS. O'DELL: Objection to form.</p> <p>24 A. I didn't -- I -- I don't know</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. All right. Those studies did</p> <p>2 not involve the perineal application of</p> <p>3 talcum powder products; is that right?</p> <p>4 MS. O'DELL: Object to the</p> <p>5 form.</p> <p>6 A. It was not a factor in the</p> <p>7 study.</p> <p>8 BY MR. ZELLERS:</p> <p>9 Q. Crocidolite and chrysotile</p> <p>10 asbestos has generally not been found in</p> <p>11 talcum powder products, correct?</p> <p>12 A. In general, that's the case.</p> <p>13 Q. Was there ever a point in time</p> <p>14 where you believe that the talcum powder</p> <p>15 products involved in this case were not</p> <p>16 contaminated with asbestos?</p> <p>17 MS. O'DELL: Objection to form,</p> <p>18 vague as to time.</p> <p>19 A. My understanding is that Imerys</p> <p>20 and their predecessors and Johnson & Johnson</p> <p>21 made significant efforts to reduce components</p> <p>22 of asbestos in their talc products over a</p> <p>23 number of years and made step-wise progress</p> <p>24 in doing that.</p>	<p style="text-align: right;">Page 149</p> <p>1 that and doesn't matter to me.</p> <p>2 BY MR. ZELLERS:</p> <p>3 Q. Do you know where the data in</p> <p>4 those exhibits come from?</p> <p>5 A. Well, they come from the two</p> <p>6 persons who are testifying who have produced</p> <p>7 them from their -- mostly from their business</p> <p>8 records.</p> <p>9 Q. Okay. So you believe that</p> <p>10 Exhibit Hopkins-28 to the Hopkins deposition</p> <p>11 and Exhibit Pier-47 to the Pier deposition</p> <p>12 come from the business records of the</p> <p>13 Johnson & Johnson Company and Imerys?</p> <p>14 A. From the most part, there was</p> <p>15 a -- there was a table that was constructed</p> <p>16 during the deposition which was sort of a</p> <p>17 piece of summary information. I don't know</p> <p>18 if it's an exhibit to the deposition or if</p> <p>19 it's something separate from that, but it</p> <p>20 would not have been from business records,</p> <p>21 but occurred at the deposition itself.</p> <p>22 MS. O'DELL: Excuse me,</p> <p>23 Dr. Carson, would you like to see a</p> <p>24 copy of exhibit -- of the Hopkins</p>

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<p>1 Exhibit Hopkins-28 and Pier 2 Exhibit Pier-47 in answering these 3 questions? 4 THE WITNESS: If that's easy to 5 do, yes. 6 MS. O'DELL: It's very easy to 7 do. This is a copy of 8 Exhibit Hopkins-28 of the Hopkins 9 deposition and Exhibit Pier-47 of the 10 Pier deposition. 11 THE WITNESS: Okay. 12 BY MR. ZELLERS: 13 Q. Dr. Carson? 14 A. Yes, sir. 15 Q. Did you make any effort to 16 investigate the alternative explanations for 17 the data that's contained in those two 18 exhibits, Exhibit Hopkins-28 and 19 Exhibit Pier-47? 20 A. Alternative explanations, I'm 21 not sure what you mean by that. 22 Q. If the Johnson & Johnson 23 company -- companies' scientists and Imerys' 24 scientists opined that those tests don't</p>	<p>1 exhibits you're looking at, 2 Exhibit Hopkins-28 and Exhibit Pier-47, were 3 included in talcum powder product sold by J&J 4 Consumer Products? 5 MS. O'DELL: Objection to the 6 form, asked and answered. 7 A. No, I don't. 8 BY MR. ZELLERS: 9 Q. Have you confirmed -- strike 10 that. 11 What amount of asbestos 12 exposure is associated with ovarian cancer? 13 A. Any. 14 Q. Your testimony under oath is 15 that any asbestos exposure is associated with 16 ovarian cancer? 17 A. Any asbestos exposure and any 18 perineal application of talcum powder is 19 associated with an increased risk for ovarian 20 cancer. 21 Q. The amount of asbestos 22 contained -- or allegedly contained within 23 the baby powder is of no consequence, 24 correct?</p>
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<p>1 actually show asbestos, you have no expertise 2 to dispute that, do you? 3 MS. O'DELL: Object to the 4 form. 5 A. No, I don't have any personal 6 expertise to dispute that. 7 BY MR. ZELLERS: 8 Q. Do you know whether or not any 9 of the talc product that is identified on 10 Exhibit Hopkins-28 and Exhibit Pier-47 was 11 actually used in the talcum powder products 12 that were sold by the Johnson & Johnson 13 Consumer Products company? 14 MS. O'DELL: Objection to form. 15 A. I -- it's my understanding that 16 some of these results, at least -- in 17 particular from the Pier deposition, that 18 some of these results were from testing that 19 was done on material that had already been 20 shipped and probably incorporated into 21 products. 22 BY MR. ZELLERS: 23 Q. Do you know whether or not any 24 of the talc that is referred to on the two</p>	<p>1 MS. O'DELL: Object to the 2 form. 3 A. No, it is of consequence, and a 4 larger dose would be a greater hazard. But 5 that doesn't mean that a low dose is not a 6 hazard. 7 BY MR. ZELLERS: 8 Q. My question is: Do you know 9 the amount of alleged asbestos exposure 10 that's associated with ovarian cancer? 11 A. No. 12 Q. Do you know the type of ovarian 13 cancer that asbestos is associated with? 14 MS. O'DELL: Object to the 15 form. 16 A. It's associated mostly with the 17 collection of epithelial ovarian cancers -- 18 BY MR. ZELLERS: 19 Q. What -- 20 A. -- primarily serous. 21 Q. Does the type of ovarian cancer 22 vary based upon the type of asbestos? 23 A. Not that I'm aware of. 24 Q. You believe that all types of</p>

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<p>1 asbestos can produce all types of ovarian 2 cancer; is that correct? 3 MS. O'DELL: Object to the 4 form. 5 A. I suspect that some forms of 6 asbestos are much more carcinogenic than 7 others, and that would be true for the 8 ovaries as well as other structures in the 9 body. 10 BY MR. ZELLERS: 11 Q. Are you able to distinguish for 12 us what types of asbestos cause or are 13 associated with what types of ovarian cancer? 14 A. I don't think I'm able to make 15 those distinctions, but the studies I just 16 read to you regarding the relationship 17 between asbestos and ovarian cancer and the 18 others on my list do indicate that there are, 19 for example, in the Acheson study, there 20 were -- there was a positive relationship 21 between both crocidolite and chrysotile 22 exposure, and the crocidolite had a greater 23 effect on ovarian cancer than the chrysotile, 24 but did not have -- they were both positive.</p>	<p>1 A. That's background information 2 and my personal knowledge. 3 Q. You are not going to give an 4 opinion on mines, mining or milling in this 5 case; is that right? 6 A. Depends on the questions. 7 Q. Well, as you sit here today, do 8 you intend to give opinions on talc mining, 9 mines or milling? 10 A. It wasn't my intention, but if 11 asked a question that I think I'm qualified 12 to answer, I'll try to do it. 13 Q. Are you an expert on talc 14 mining and milling? 15 A. I'm an expert on industrial 16 processes in general, and if -- I have some 17 personal understanding of talc mining and 18 milling. 19 Q. Have you been personally 20 involved in talc mining and milling? 21 A. I haven't been involved in it; 22 I've observed it. 23 Q. Do you consider yourself to be 24 an expert in talc mining and milling?</p>
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<p>1 Q. What type of ovarian cancer? 2 A. That, I don't know at the 3 moment. I could look in the paper and see if 4 it's listed. 5 Q. There are a number of different 6 types of ovarian cancer; is that right? 7 A. That's correct. 8 Q. You are not familiar with J&J 9 Consumer Products' procedures for milling or 10 mining; is that right? 11 MS. O'DELL: Object to the 12 form. 13 A. I'm familiar with some of their 14 procedures, yes. 15 BY MR. ZELLERS: 16 Q. Are you familiar with their 17 testing of source mines? 18 A. To some extent. 19 MS. O'DELL: Object to the 20 form. 21 BY MR. ZELLERS: 22 Q. Is it set forth in your report, 23 or is that just background information that 24 you looked at?</p>	<p>1 MS. O'DELL: Objection, asked 2 and answered. 3 A. No, I don't. 4 BY MR. ZELLERS: 5 Q. You have no independent basis 6 to say that cosmetic talc contains asbestos, 7 correct? 8 MS. O'DELL: Object to the 9 form. 10 A. What do you mean by independent 11 basis? 12 BY MR. ZELLERS: 13 Q. You have not done any testing 14 of talcum powder to determine whether it 15 contains asbestos or not; is that right? 16 A. No. All of my understanding is 17 based on other sources. 18 Q. And those other sources would 19 be, in part, the testing that was done by 20 Longo; is that right? 21 A. Yes, as well as the testing 22 that's reported in the -- in the literature 23 section as the Imerys test results and 24 quality control materials.</p>

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<p>1 Q. You're looking now back at the</p> <p>2 Pier Exhibit Pier-47 and the Hopkins</p> <p>3 Exhibit Hopkins-28; is that right?</p> <p>4 A. I was actually referring to the</p> <p>5 Imerys documents that are referenced toward</p> <p>6 the end of the literature exhibit to my</p> <p>7 report, but certainly the Exhibit Pier-47</p> <p>8 would be included there.</p> <p>9 Q. You have no independent basis</p> <p>10 to say that cosmetic talcum powder contains</p> <p>11 fibrous talc, correct?</p> <p>12 MS. O'DELL: Object to the</p> <p>13 form.</p> <p>14 A. I have no independent basis,</p> <p>15 no.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. You're familiar with the</p> <p>18 limitations of the research on a potential</p> <p>19 link between asbestos and ovarian cancer; is</p> <p>20 that right?</p> <p>21 MS. O'DELL: Object to the</p> <p>22 form.</p> <p>23 A. I'm familiar with some research</p> <p>24 limitations in that question, yes.</p>	<p>1 BY MR. ZELLERS:</p> <p>2 Q. The Reid paper that I've handed</p> <p>3 you, what we've marked as Exhibit 17, looks</p> <p>4 at the issue: Does exposure to asbestos</p> <p>5 cause ovarian cancer.</p> <p>6 Is that right?</p> <p>7 A. Yes.</p> <p>8 Q. They talk about in terms of</p> <p>9 limitations on the first page, right-hand</p> <p>10 column, they say: Studies that have examined</p> <p>11 this issue have been limited for two major</p> <p>12 reasons.</p> <p>13 Is that right?</p> <p>14 A. Yes.</p> <p>15 Q. Number one, small number of</p> <p>16 cases, much fewer women than men have been</p> <p>17 exposed to asbestos, particularly in more</p> <p>18 heavily exposed occupational settings where</p> <p>19 relative risks are higher; is that right?</p> <p>20 A. Yes.</p> <p>21 Q. How many of these studies --</p> <p>22 well, strike that.</p> <p>23 Would you agree that the</p> <p>24 studies in this area have been primarily</p>
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<p>1 BY MR. ZELLERS:</p> <p>2 Q. You agree that research on the</p> <p>3 potential relationship between asbestos and</p> <p>4 ovarian cancer has only considered a small</p> <p>5 number of cases; is that right?</p> <p>6 MS. O'DELL: Object to the</p> <p>7 form.</p> <p>8 A. Well, it's considered thousands</p> <p>9 of cases. Certainly in terms of the number</p> <p>10 of women who have experienced ovarian cancer</p> <p>11 it's small, but it's significant, and that's</p> <p>12 where we get research from that answers</p> <p>13 important questions.</p> <p>14 BY MR. ZELLERS:</p> <p>15 Q. Are you familiar with the Reid</p> <p>16 paper, 2011?</p> <p>17 A. Yes, but it's been a while</p> <p>18 since I've looked at it.</p> <p>19 Q. Well, I'll hand you a copy.</p> <p>20 We'll mark it as Exhibit 17.</p> <p>21 (Carson Deposition Exhibit 17</p> <p>22 marked.)</p> <p>23 MS. O'DELL: Thank you.</p> <p>24 ///</p>	<p>1 related to occupational exposure?</p> <p>2 A. Primarily, yes.</p> <p>3 Q. How many total women have been</p> <p>4 studied?</p> <p>5 MS. O'DELL: Object to the</p> <p>6 form. In this study, in this paper,</p> <p>7 or are you talking about in general?</p> <p>8 MR. ZELLERS: In general.</p> <p>9 A. I don't know the answer to</p> <p>10 that.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. How many women have been</p> <p>13 studied in nonoccupational studies?</p> <p>14 A. Well, very few in comparison to</p> <p>15 the occupational studies.</p> <p>16 Q. Are you aware of the</p> <p>17 difficulties that have existed over time in</p> <p>18 distinguishing between peritoneal</p> <p>19 mesothelioma and ovarian cancer?</p> <p>20 A. Yes.</p> <p>21 Q. What are those difficulties?</p> <p>22 A. There is a potential</p> <p>23 misclassification of one as the other because</p> <p>24 they have very common habits. They look very</p>

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<p>1 similar under light microscopy, and they're 2 often difficult to distinguish, even by a 3 pathologist, unless special tests are used. 4 Often these cases occur in 5 places where they don't have the access to 6 special test equipment that can definitively 7 distinguish, and so they are classified and 8 we move on. 9 Q. Another limitation of any 10 studies in this area relate to the inability 11 to account for nonoccupational risk factors 12 for ovarian cancer other than age; is that 13 right? 14 MS. O'DELL: Object to the 15 form. 16 A. Are you reading also from this 17 paper or -- 18 BY MR. ZELLERS: 19 Q. I was looking now at the 20 Camargo paper. Are you familiar with the 21 Camargo paper? 22 A. If you have a copy of that, I'd 23 like to look at it, if I'm going to answer 24 questions about it.</p>	<p>1 take a minute to refresh yourself on 2 the page -- 3 MR. ZELLERS: I'm looking under 4 Discussion. 5 MS. O'DELL: -- please feel 6 free to do that. 7 Excuse me, sir, I was talking. 8 If you need to review the paper, 9 Dr. Carson, please feel free to do 10 that. 11 MR. ZELLERS: This doctor has 12 given 35 depositions. He is perfectly 13 capable of handling himself. He does 14 not need your advice as we go along. 15 MS. O'DELL: Nor do I, Michael. 16 So I'm going to deal with this witness 17 in the way I choose, which is 18 perfectly appropriate. If Dr. Carson 19 needs to review the paper, he's going 20 to review the paper. You may ask him 21 questions, he'll be happy to respond. 22 MR. ZELLERS: Your job is not 23 to coach the witness; your job is to 24 make objections as to form or</p>
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<p>1 Q. All right. This is a paper in 2 2011. We'll mark it as Exhibit 18. 3 (Carson Deposition Exhibit 18 4 marked.) 5 BY MR. ZELLERS: 6 Q. Here the authors also looked at 7 the issue of occupational exposure to 8 asbestos and ovarian cancer; is that right? 9 A. Yes. 10 Q. If you turn to page 216 -- I'm 11 sorry, 1216, second-to-last paragraph before 12 the conclusion: A further limitation of our 13 analysis was its inability to account for 14 nonoccupational risk factors for ovarian 15 cancer other than age. 16 Is that identified by the 17 authors as a limitation? 18 A. Yes, it is. 19 Q. Under -- if you go a page back, 20 1215, under Discussion, in the second 21 paragraph, the authors talk about other 22 studies that have been done in this area, 23 including Edelman; is that right? 24 MS. O'DELL: If you need to</p>	<p>1 foundation, not to make speaking 2 objections and coaching of the 3 witness. 4 MS. O'DELL: If you have a 5 question, I'm sure Dr. Carson would be 6 happy to address it. 7 MR. ZELLERS: I've asked him 8 the question. 9 MS. O'DELL: Would you mind 10 repeating the question, please? 11 MR. ZELLERS: Sure. 12 THE WITNESS: I don't remember 13 the question. 14 MR. ZELLERS: Okay. I'll be 15 happy to repeat it. 16 BY MR. ZELLERS: 17 Q. Dr. Carson, you've looked at 18 this Camargo paper; is that right? 19 A. Yes. 20 Q. In their discussion, they talk 21 about other research, including research done 22 by Edelman; is that right? 23 A. Are you at the top of the 24 middle column on --</p>

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<p>1 Q. I'm looking under Discussion.</p> <p>2 A. Yes.</p> <p>3 Q. The first -- well, the second</p> <p>4 paragraph.</p> <p>5 A. Second paragraph, yes.</p> <p>6 Q. The magnitude of the pooled</p> <p>7 estimate is similar to that reported by</p> <p>8 Edelman; is that right?</p> <p>9 A. Correct. Correct.</p> <p>10 Q. Then they state: They</p> <p>11 concluded, however, that despite the positive</p> <p>12 and significant association, there was</p> <p>13 insufficient information to infer that</p> <p>14 ovarian cancers were caused by occupational</p> <p>15 exposure to asbestos because of concerns</p> <p>16 about tumor misclassification, inappropriate</p> <p>17 comparison populations and the failure to</p> <p>18 take into account for known risk factors.</p> <p>19 Did I read that --</p> <p>20 A. You read that correctly.</p> <p>21 Q. All right. Are women who use</p> <p>22 talc perineally at greater risk of</p> <p>23 mesothelioma?</p> <p>24 A. I can't say that they are, but</p>	<p>1 BY MR. ZELLERS:</p> <p>2 Q. -- if your theory is correct?</p> <p>3 MS. O'DELL: Object to the</p> <p>4 form.</p> <p>5 A. There may have been higher</p> <p>6 rates of ovarian cancers, but you have to</p> <p>7 also understand that the latency period for</p> <p>8 ovarian cancer is pretty long. It's greater</p> <p>9 than 20 years, often as long as 40 years.</p> <p>10 And so we're still dealing with cancers that</p> <p>11 may have started back in the '70s.</p> <p>12 BY MR. ZELLERS:</p> <p>13 Q. Would you agree that exposure</p> <p>14 to asbestos through a perineal cosmetic talc</p> <p>15 use is different from the heavy occupational</p> <p>16 exposure that has primarily been researched?</p> <p>17 MS. O'DELL: Objection to form.</p> <p>18 A. Yes. I agree with that.</p> <p>19 BY MR. ZELLERS:</p> <p>20 Q. Are you an expert and</p> <p>21 knowledgeable about cleavage fragments?</p> <p>22 A. I'm not.</p> <p>23 Q. If I went through a series of</p> <p>24 questions and asked you to differentiate</p>
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<p>1 they may be.</p> <p>2 Q. Wouldn't you expect to find</p> <p>3 higher rates of other cancers in women using</p> <p>4 talc like mesothelioma if they are being</p> <p>5 exposed to substantial amounts of asbestos?</p> <p>6 A. Well, we may -- we may be</p> <p>7 seeing some mesotheliomas that are</p> <p>8 misclassified as ovarian cancers, or we may</p> <p>9 be seeing mesotheliomas and not relating talc</p> <p>10 application as a pertinent contributor to</p> <p>11 that case.</p> <p>12 Q. You told us earlier that you</p> <p>13 thought that there may have been more</p> <p>14 asbestos in talcum powders in the 1970s; is</p> <p>15 that right?</p> <p>16 MS. O'DELL: Objection to form.</p> <p>17 A. I think I said there have been</p> <p>18 step-wise improvements, and I -- but I agree</p> <p>19 with that statement.</p> <p>20 BY MR. ZELLERS:</p> <p>21 Q. Shouldn't we have seen higher</p> <p>22 rates of ovarian cancer in the earlier</p> <p>23 studies --</p> <p>24 MS. O'DELL: Object --</p>	<p>1 between cleavage fragments and asbestos</p> <p>2 fibers, you would defer that to other</p> <p>3 experts?</p> <p>4 A. I would.</p> <p>5 Q. You also claim that the</p> <p>6 presence of carcinogenic metals, including</p> <p>7 chromium, cobalt and nickel in talc, adds to</p> <p>8 its carcinogenicity; is that right?</p> <p>9 A. That is right.</p> <p>10 Q. Do you have an opinion or</p> <p>11 knowledge as to the amounts of chromium,</p> <p>12 cobalt and nickel, if any, in talc?</p> <p>13 A. Those metal elements are</p> <p>14 included as -- usually as impurities or in</p> <p>15 very small quantities in some deposits and</p> <p>16 are present in small amounts.</p> <p>17 Q. Do you have any idea how much</p> <p>18 of these metals, if any, reaches a woman's</p> <p>19 ovaries each time they use talc?</p> <p>20 A. I can't tell you how much, but</p> <p>21 I can tell you that some does, and it is --</p> <p>22 it remains in the talc until long after it</p> <p>23 reaches the ovaries.</p> <p>24 Q. Chromium, cobalt and nickel are</p>

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<p>1 natural elements; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. They are naturally in our</p> <p>4 bodies; is that right?</p> <p>5 A. That's correct.</p> <p>6 Q. They are present in food,</p> <p>7 drinking water, bottled water, vitamins; is</p> <p>8 that right?</p> <p>9 A. To some extent.</p> <p>10 Q. Do you have any evidence that</p> <p>11 the blood or tissue levels of any trace heavy</p> <p>12 metals are higher in genital talc users</p> <p>13 compared to nonusers?</p> <p>14 MS. O'DELL: Object to the</p> <p>15 form.</p> <p>16 A. I do not.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. As we discussed when we talked</p> <p>19 about asbestos, you cannot evaluate the</p> <p>20 potential effects of exposure to a substance</p> <p>21 without factoring in the amount of exposure;</p> <p>22 is that right?</p> <p>23 MS. O'DELL: Object to the</p> <p>24 form.</p>	<p>1 to chromium, cobalt or nickel or any other</p> <p>2 heavy metal; is that right?</p> <p>3 A. That is correct.</p> <p>4 Q. That answer to that question</p> <p>5 would be true if I asked you about the</p> <p>6 different fragrance chemicals, correct?</p> <p>7 MS. O'DELL: Object to the</p> <p>8 form.</p> <p>9 A. Also true.</p> <p>10 BY MR. ZELLERS:</p> <p>11 Q. You did a risk assessment in</p> <p>12 this matter; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. Do you agree that a complete</p> <p>15 and proper risk assessment involves four</p> <p>16 elements?</p> <p>17 MS. O'DELL: Object to the</p> <p>18 form.</p> <p>19 A. Not necessarily.</p> <p>20 BY MR. ZELLERS:</p> <p>21 Q. Well, you have to identify a</p> <p>22 potential hazard; is that right?</p> <p>23 A. Yes.</p> <p>24 Q. You've got to do some type of</p>
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<p>1 A. It's useful to factor in the</p> <p>2 amount if the amount is known. If the amount</p> <p>3 is not known, it's not necessarily required</p> <p>4 to draw conclusions.</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. In this case, you do not know</p> <p>7 the amount, be it chromium, cobalt and/or</p> <p>8 nickel; is that right?</p> <p>9 MS. O'DELL: Objection to the</p> <p>10 form.</p> <p>11 Excuse me. Dr. Carson, as you</p> <p>12 know, is not being offered as a</p> <p>13 case-specific expert, so that question</p> <p>14 sounds like a specific patient, and so</p> <p>15 I would -- that's my objection.</p> <p>16 A. I do not know the amount, but</p> <p>17 my opinion is that any within the</p> <p>18 microenvironment of the inflammatory process</p> <p>19 that is occurring due to talc sequestration</p> <p>20 is contributing to the carcinogenic</p> <p>21 potential.</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. But you don't know for any</p> <p>24 individual plaintiff their level of exposure</p>	<p>1 dose-response assessment; is that right?</p> <p>2 A. Not necessarily.</p> <p>3 Q. You --</p> <p>4 MS. O'DELL: Excuse me. If you</p> <p>5 finished -- if you need to,</p> <p>6 Dr. Carson, if you're not finished.</p> <p>7 If you're finished, fine. Sorry.</p> <p>8 A. A qualitative risk assessment</p> <p>9 does not necessarily require a dose-response</p> <p>10 in order to reach valid conclusions.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. It is not necessary to do a</p> <p>13 dose-response assessment as part of a risk</p> <p>14 assessment. Is that your testimony under</p> <p>15 oath?</p> <p>16 A. It's not always necessary.</p> <p>17 Q. Was it necessary in this case?</p> <p>18 A. Well, I think there is an</p> <p>19 aspect of dose-response that was performed in</p> <p>20 the risk assessment process here.</p> <p>21 Q. What dose-response assessment</p> <p>22 did you make with respect to chromium, cobalt</p> <p>23 and nickel and any other heavy metal?</p> <p>24 A. There's no information</p>

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<p>1 available to do a dose-response estimate for 2 those metals. 3 Q. What information did you rely 4 or use, if any, to make a dose-response 5 assessment with respect to any fragrance 6 chemicals? 7 MS. O'DELL: Objection, form. 8 A. There is no information 9 available to do a dose-response estimate for 10 the fragrances. 11 BY MR. ZELLERS: 12 Q. Did you do any type of exposure 13 assessment in this case? 14 MS. O'DELL: Object to the 15 form, vague. 16 A. I'm not sure exactly what 17 you're -- what you're asking by exposure 18 assessment. 19 BY MR. ZELLERS: 20 Q. Well, an exposure assessment is 21 also part of a risk assessment; is that 22 right? 23 A. In this risk assessment, I 24 considered studies that are reported in the</p>	<p>1 and the metals were there as the baseline 2 component of the talc formation that they 3 came from. 4 BY MR. ZELLERS: 5 Q. You do not know the amounts of 6 either the heavy metals or the fragrance 7 chemicals in the talcum powder at issue in 8 this case, correct? 9 A. That's -- that's correct, I 10 don't. 11 Q. You do not know -- well, strike 12 that. I'll withdraw that. 13 You brought with you an IARC 14 monograph; is that right? 15 A. I have a couple of them. 16 Q. All right. 17 MS. O'DELL: Are we going to -- 18 are you going to move to -- 19 MR. ZELLERS: We can take a 20 break if you'd like. 21 MS. O'DELL: Yeah, it's been 22 about an hour and a half. 23 MR. ZELLERS: Sure. 24 THE VIDEOGRAPHER: We're off</p>
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<p>1 scientific and medical literature which have 2 reported the assessment of exposure in these 3 cases in various forms, and I considered 4 those exposure assessments as being valid as 5 reported and considered them as a whole. 6 Q. Did you look at any exposure 7 assessment specific to the alleged heavy 8 metals contained in talcum powder? 9 MS. O'DELL: Object to the 10 form. 11 A. No, I did not. 12 BY MR. ZELLERS: 13 Q. Did you look at any exposure 14 assessment with respect to any fragrance 15 chemicals contained within talcum powder? 16 MS. O'DELL: Object to the 17 form. 18 A. With respect to the fragrance 19 chemicals and the heavy metals, the only 20 exposure assessment that I was able to do was 21 verify that these things were present in 22 materials. 23 The fragrances are always 24 present in whatever form they were added in,</p>	<p>1 the record 12:32, end of Tape 2. 2 (Recess taken, 12:32 p.m. to 3 1:38 p.m.) 4 THE VIDEOGRAPHER: We're on the 5 record, 1:38, beginning of Tape 3. 6 BY MR. ZELLERS: 7 Q. Dr. Carson, when we left, we 8 were talking about the trace metals and 9 fragrance chemicals in talcum powder, 10 correct? 11 A. Yes. 12 Q. You do not know how much of 13 these trace metals or fragrance chemicals 14 reach the ovaries, correct? 15 A. I don't know specifically how 16 much reaches it, but if I know it's a 17 component of the talc, and if I know the talc 18 reaches it, then I know some of the metals 19 and the fragrances reach it. 20 Q. You don't know the component or 21 the amount of either the trace metals or the 22 fragrance chemicals in the baby powder, 23 correct? 24 A. That's correct.</p>

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<p>1 Q. You do not know the exposure of 2 any of the women who are plaintiffs in this 3 litigation to the talcum powder, correct? 4 MS. O'DELL: Individual women? 5 MR. ZELLERS: Yes, individual 6 women. 7 A. I don't, no. 8 BY MR. ZELLERS: 9 Q. You brought with you an IARC 10 monograph, and I think you've got several 11 monographs that are on your literature list; 12 is that right? 13 A. That's correct. 14 Q. Generally, IARC classifies 15 chemicals and agents from Group 1, 16 carcinogenic to humans, down to Group 4, 17 probably not carcinogenic to humans; is that 18 right? 19 A. That's correct. 20 Q. Does the classification of a 21 substance as a known probable or possible 22 carcinogen by IARC, and IARC is International 23 Agency for Research on Cancer, or by the 24 National Toxicology Program or the U.S.</p>	<p>1 BY MR. ZELLERS: 2 Q. What -- would you agree that, 3 in general, metals can differ in their 4 toxicity and potential carcinogenicity based 5 on their form? 6 A. Yes. 7 Q. Do you know the forms of 8 chromium, nickel and cobalt detected in 9 cosmetic talc? 10 A. There's -- metal ions are 11 usually incorporated in the mineral lattice, 12 and so they are part of the magnesium 13 silicate crystal. 14 Q. I'm not sure if that answers my 15 question, and if it does, I don't understand, 16 so let me ask again. 17 Do you know the forms, and by 18 that I mean valence state, of chromium or 19 nickel or cobalt that have been detected in 20 cosmetic talc? 21 A. Oh, the valence state? 22 Q. Yes, sir. 23 A. I don't know specifically, but 24 that's dependent on the surrounding structure</p>
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<p>1 Environmental Protection Agency, mean that 2 the substance can cause all types of cancers 3 in humans by any exposure route? 4 MS. O'DELL: Object to the 5 form. 6 A. No. 7 BY MR. ZELLERS: 8 Q. There are different cancers 9 that may be associated with different 10 chemicals or agents; is that right? 11 A. And different routes of 12 exposure. 13 Q. You can have an agent that is a 14 carcinogen or a probable or possible 15 carcinogen for one type of cancer, but not 16 for another type of cancer, correct? 17 A. That's correct. 18 Q. You can have an agent or a 19 chemical that's a carcinogen for one route of 20 exposure for a chemical or agent but is not 21 carcinogenic for a different route of 22 exposure, correct? 23 MS. O'DELL: Objection to form. 24 A. Yes.</p>	<p>1 that the metals are contained in, and metals 2 can assume a different valence state 3 depending on the redox environment. 4 Q. You are not, at least in this 5 litigation today, expressing any opinion as 6 to the valence state of chromium that may be 7 found in cosmetic talc, correct? 8 MS. O'DELL: Object to the 9 form. 10 A. No, I'm not. 11 BY MR. ZELLERS: 12 Q. Your second opinion is that the 13 perineal use of talcum powder results in 14 direct exposure to the ovaries either via 15 inhalation or migration through the female 16 reproductive tract; is that right? 17 A. Well, it's primarily through 18 the female reproductive tract. The 19 inhalation exposure would be a secondary 20 route. 21 Q. Let me ask you a couple of 22 questions about inhalation exposure. 23 You do not cite any studies in 24 the body of your report evidencing that</p>

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<p>1 talcum powder can reach the ovaries through 2 inhalation, correct? 3 MS. O'DELL: Object to the 4 form. 5 A. That is correct, although 6 there -- yes, that's correct. 7 BY MR. ZELLERS: 8 Q. You have never performed any 9 study yourself pertaining to whether inhaled 10 talc can migrate to the ovaries; is that 11 right? 12 A. I have not, although it has 13 been used as an explanation of how talc 14 particles might have reached the ovaries in 15 persons who did not have another form of 16 exposure. 17 Q. If inhalation is the exposure 18 path for talc, shouldn't the lungs bear more 19 of a burden? 20 A. Yes. 21 Q. Why, then, isn't there an 22 epidemic of mesothelioma in women who use 23 talcum powder? 24 A. Because the primary route is</p>	<p>1 A. The -- I'm sorry. The Heller 2 study was talc, which I didn't cite here. 3 Halme was a retrograde menstruation study via 4 the fallopian tubes, and Sjösten was starch 5 particles. 6 Q. The only study -- and this is 7 not one that you cited, but you've now 8 referred to that involved talc, was Heller; 9 is that right? 10 A. Well, it looked at -- it didn't 11 look at transport inasmuch as it looked at 12 the presence of talc particles in the ovaries 13 and found them with or without the history of 14 talc powder use. 15 Q. Heller looked at 24 patients; 16 is that right? 17 A. I don't know, but that sounds 18 about right. 19 Q. Half of them had a history of 20 using talc products, half did not? 21 MS. O'DELL: Object to form. 22 A. That's correct. 23 BY MR. ZELLERS: 24 Q. Heller found talc in the</p>
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<p>1 perineal via the reproductive tract. 2 Q. You discuss that on page 7 of 3 your report; is that right? 4 A. Yes. 5 Q. You cite a number of studies 6 for the proposition that talc can be 7 transported from the perineum to the upper 8 reproductive tract and body cavity; is that 9 right? 10 A. That's correct. 11 Q. None of the articles that you 12 cite actually looked at whether talc can 13 migrate from perineal application through the 14 fallopian tubes to the ovaries, did they? 15 A. Let me just refresh my memory 16 for a moment here. Egli was carbon black. 17 Venter was radioactive technetium labeled 18 albumin. Let me see. Blumenkrantz -- I have 19 my notes here. 20 Yeah, I can't remember what the 21 substance was in Blumenkrantz. Sjösten, 22 starch -- yeah, Blumenkrantz was retrograde 23 menstruation. Halme was talc. 24 Q. Which study was talc?</p>	<p>1 tissues of all 24 patients; is that right? 2 A. That is correct. 3 Q. I believe we covered this 4 before, but just to confirm: There are no 5 published articles that you're aware of that 6 show granulomas, fibrosis or adhesions 7 anywhere in the reproductive tract of a woman 8 as a result of external genital talc 9 application, correct? 10 MS. O'DELL: Object to the 11 form. 12 A. I believe that's the case, 13 although there have been granulomas found in 14 some cases of cancer where they reported 15 having used talc. 16 BY MR. ZELLERS: 17 Q. Of the cases or the studies you 18 cited here, Egli, that involved just three 19 women, correct? 20 A. That was just -- that was an 21 experimental study of the transport of carbon 22 particles. 23 Q. The women were in a lithotomy 24 position; is that right?</p>

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<p style="text-align: right;">Page 186</p> <p>1 A. That's correct.</p> <p>2 Q. And that means that they had</p> <p>3 their legs up in the air, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Those conditions -- well,</p> <p>6 strike that.</p> <p>7 They were injected with</p> <p>8 oxytocin; is that right?</p> <p>9 A. It is.</p> <p>10 Q. That was to aid in the</p> <p>11 transport of the particles, correct?</p> <p>12 MS. O'DELL: Object to the</p> <p>13 form.</p> <p>14 A. I believe that was the author's</p> <p>15 theory.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. Those are different</p> <p>18 circumstances or conditions from a woman who</p> <p>19 would apply a talc to her genital area</p> <p>20 standing up, correct?</p> <p>21 A. Well, they are, but I'm not</p> <p>22 sure that that position is really pertinent</p> <p>23 to the migration of particles through the</p> <p>24 reproductive tract.</p>	<p style="text-align: right;">Page 188</p> <p>1 of all these studies -- that they were using</p> <p>2 various particles that could be detected at</p> <p>3 the other end, and so this was an attempt to</p> <p>4 do an experimental study which would cause no</p> <p>5 harm that would give them an answer regarding</p> <p>6 transport through the reproductive tract.</p> <p>7 Q. In this study, particles were</p> <p>8 introduced into the reproductive tract, not</p> <p>9 externally; is that right?</p> <p>10 MS. O'DELL: Object to the</p> <p>11 form.</p> <p>12 A. That is correct.</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. Women were given Pitocin to</p> <p>15 stimulate uterine contractions; is that</p> <p>16 right?</p> <p>17 A. That's the same as oxytocin.</p> <p>18 Q. And that's a yes, correct?</p> <p>19 A. Yes.</p> <p>20 Q. Again, as with the Egli study,</p> <p>21 the women were inverted in the Trendelenburg</p> <p>22 position with their head down, legs up when</p> <p>23 the particles were administered; is that</p> <p>24 right?</p>
<p style="text-align: right;">Page 187</p> <p>1 Q. Is it your pos- -- is it your</p> <p>2 testimony that if a woman is in a lithotomy</p> <p>3 position with their legs up into the air,</p> <p>4 that that is comparable with respect to the</p> <p>5 migration of talc to a woman who's standing</p> <p>6 up and using it in her perineal region?</p> <p>7 A. It may be.</p> <p>8 Q. Are you an expert on that?</p> <p>9 A. I'm not.</p> <p>10 Q. The authors in Egli, they</p> <p>11 stated it was possible that the study</p> <p>12 observed false positives due to sample</p> <p>13 contamination because they failed to use</p> <p>14 liquid or filter blanks as negative controls,</p> <p>15 correct?</p> <p>16 A. I don't recall that, but that</p> <p>17 may be the case.</p> <p>18 Q. You refer to a study by Venter.</p> <p>19 That involved a radioactive particulate</p> <p>20 matter, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Did not involve talc particles,</p> <p>23 correct?</p> <p>24 A. The point of the study was --</p>	<p style="text-align: right;">Page 189</p> <p>1 A. I believe so.</p> <p>2 Q. Is it possible that the</p> <p>3 radionuclides can leach from the particles?</p> <p>4 A. I don't know the answer to</p> <p>5 that, but it was radioactive technetium that</p> <p>6 was bound to albumin.</p> <p>7 Q. The Sjösten study that you</p> <p>8 cite, that did not use -- involve the</p> <p>9 perineal use of talc, but an exam with a</p> <p>10 force to the cervix; is that right?</p> <p>11 A. Excuse me. An exam with what?</p> <p>12 Q. So it involved an exam with</p> <p>13 force to the cervix?</p> <p>14 MS. O'DELL: Object to the</p> <p>15 form.</p> <p>16 A. Well, this was -- this was done</p> <p>17 as an experimental study on women who were</p> <p>18 scheduled to get hysterectomies and they did</p> <p>19 it on some women one day prior to the</p> <p>20 hysterectomy and another group of women four</p> <p>21 days prior to the hysterectomy, and they used</p> <p>22 gloves that were powdered with starch and</p> <p>23 gloves that were not powdered with starch.</p> <p>24 And so they had what's called a</p>

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<p style="text-align: right;">Page 190</p> <p>1 Latin square design, and they were able at 2 the point of the hysterectomy of taking 3 samples of the fallopian tubes and washing 4 them to determine whether or not particles 5 were found in the tubes. 6 BY MR. ZELLERS: 7 Q. What they actually found was 8 that, whether the women were examined with 9 gloves with the starch particles or not, they 10 found starch particles in both, both groups, 11 correct? 12 A. It is true. 13 Q. Tubal ligation, you refer to 14 tubal ligation and use that or purport to say 15 that that supports your migration theory, 16 correct? 17 A. It does. 18 Q. Your testimony is that for 19 patients who have had a tubal ligation, that 20 they are at a lesser risk of the talc -- let 21 me withdraw that. 22 Explain to us very briefly why 23 you believe that tubal ligation supports your 24 migration theory.</p>	<p style="text-align: right;">Page 192</p> <p>1 Q. In fact, in Terry -- well, and 2 let me mark it for you so you've got it in 3 front of you. 4 THE WITNESS: Okay. I'm going 5 to move this binder for the time 6 being, if you don't mind. 7 MR. ZELLERS: Oh, yes, I'll 8 hand you the articles that I refer to, 9 but if you need it, just pull it out. 10 THE WITNESS: Thank you. 11 (Carson Deposition Exhibit 19 12 marked.) 13 BY MR. ZELLERS: 14 Q. Deposition Exhibit 19 is the 15 2013 Terry meta-analysis that you referred to 16 in your report; is that right? 17 A. Yes. 18 Q. That's a pooled analysis of 19 eight studies; is that right? 20 A. Yes. 21 Q. Okay. This pooled analysis of 22 eight studies relating to genital powder use 23 and the risk of ovarian cancer shows no 24 variation in the risk in talc users based on</p>
<p style="text-align: right;">Page 191</p> <p>1 A. If the pathway of exposure of 2 the ovaries that results in ovarian cancer is 3 via the reproductive tract, then tubal 4 ligation, which closes off the fallopian 5 tubes, would interrupt that pathway and 6 result in reduced exposure; therefore, you 7 would expect a reduced incidence of cancer in 8 those women. 9 Q. In fact, though, that is not 10 what has been reported or at least that has 11 not been consistently reported in the 12 studies; is that right? 13 A. Well, it actually has been a 14 positive factor in a number of the 15 epidemiologic studies that have looked at the 16 ovarian cancer incidence and have been able 17 to include tubal ligation as a historical 18 factor in their analysis. 19 Q. Did you look at the Terry 2013 20 meta-analysis? 21 A. Yes. 22 Q. You cite that in support of 23 your positions in this case; is that right? 24 A. I did.</p>	<p style="text-align: right;">Page 193</p> <p>1 whether they had a tubal ligation or 2 hysterectomy; is that right? 3 A. I think that's the conclusion 4 of the authors here, but it's not the 5 conclusion of the individual authors of the 6 studies who did the original investigations. 7 Q. Well, it is the conclusion of 8 the authors based upon their meta-analysis of 9 eight studies; is that right? 10 MS. O'DELL: Object to the 11 form. 12 A. Let me just check that. 13 (Document review.) 14 A. Yes. 15 BY MR. ZELLERS: 16 Q. If you look at pages 819, 17 carried over to 820, I'm reading: Our 18 finding of slightly attenuated associations 19 following exclusion of women with powder 20 exposure after tubal ligation or hysterectomy 21 are not supportive of this hypothesis, but 22 risk estimates in this subgroup analysis may 23 have randomly differed from those including 24 all women because of the reduction in sample</p>

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<p>1 size.</p> <p>2 Is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Essentially, looking at these</p> <p>5 eight studies in this meta-analysis, Terry</p> <p>6 did not find that exposure to genital powder</p> <p>7 applications that occurred before tubal</p> <p>8 ligation or hysterectomy made any substantive</p> <p>9 difference in the results; is that right?</p> <p>10 A. Yes, but the point is that the</p> <p>11 authors didn't find that it did not make a</p> <p>12 difference either. They -- they ended up</p> <p>13 with a study with reduced numbers that they</p> <p>14 couldn't make determinations about.</p> <p>15 Q. If, though, the migration</p> <p>16 theory is correct, you would expect that</p> <p>17 there would be a reduction in the incidence</p> <p>18 of ovarian cancer for women who have had a</p> <p>19 tubal ligation or hysterectomy; is that</p> <p>20 right?</p> <p>21 MS. O'DELL: Object to the</p> <p>22 form.</p> <p>23 A. Yes, that is correct.</p> <p>24 ///</p>	<p>1 THE WITNESS: Thank you.</p> <p>2 MS. O'DELL: Thank you.</p> <p>3 BY MR. ZELLERS:</p> <p>4 Q. This is also a study,</p> <p>5 Exhibit 20, Cramer 2016, that you cite as</p> <p>6 supportive of your opinions in this case,</p> <p>7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. Cramer actually looked at</p> <p>10 whether or not there was any greater</p> <p>11 association of talc use and ovarian cancer</p> <p>12 and whether or not women who had a tubal</p> <p>13 ligation or hysterectomy had a reduced</p> <p>14 incidence of the disease; is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. Turn to page 337, and then it</p> <p>17 carries over to 339. They're talking --</p> <p>18 they, being the authors -- of their results,</p> <p>19 and I'm reading just at the very bottom of</p> <p>20 337, carried over to 339: By test for</p> <p>21 interaction, column 3, the association was</p> <p>22 significantly greater for women who were</p> <p>23 African-American, had no personal history of</p> <p>24 breast cancer, had a tubal ligation or</p>
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<p>1 BY MR. ZELLERS:</p> <p>2 Q. And that was not found in the</p> <p>3 Terry meta-analysis that you cite; is that</p> <p>4 right?</p> <p>5 MS. O'DELL: Object to the</p> <p>6 form.</p> <p>7 A. That is correct, but it was</p> <p>8 found in the baseline studies that were, in</p> <p>9 part, included in this meta-analysis.</p> <p>10 BY MR. ZELLERS:</p> <p>11 Q. Are you -- you also cite the</p> <p>12 Cramer study, 2016; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. I've got a few questions for</p> <p>15 you on the Cramer study, but let me just ask,</p> <p>16 since we're at this part right now.</p> <p>17 Do you have the Cramer study?</p> <p>18 I'll hand it to you.</p> <p>19 A. If you have a copy, I'd</p> <p>20 appreciate it.</p> <p>21 MR. ZELLERS: Sure. We'll mark</p> <p>22 the Cramer study as Exhibit 20.</p> <p>23 (Carson Deposition Exhibit 20</p> <p>24 marked.)</p>	<p>1 hysterectomy.</p> <p>2 Is that right?</p> <p>3 MS. O'DELL: Object to the</p> <p>4 form.</p> <p>5 A. Beginning on page 337?</p> <p>6 BY MR. ZELLERS:</p> <p>7 Q. Yes.</p> <p>8 A. I'm sorry, if you could --</p> <p>9 Q. Sure. At the very end of 337.</p> <p>10 A. Okay.</p> <p>11 Q. So they're looking at --</p> <p>12 A. Oh, by tests for interaction.</p> <p>13 Q. Yes.</p> <p>14 A. Yeah.</p> <p>15 Q. So if your migration theory is</p> <p>16 correct, you would expect there to be a lower</p> <p>17 incidence of ovarian cancer in women who have</p> <p>18 had a tubal ligation or hysterectomy,</p> <p>19 correct?</p> <p>20 MS. O'DELL: Object to the</p> <p>21 form.</p> <p>22 A. That is correct.</p> <p>23 BY MR. ZELLERS:</p> <p>24 Q. All right. Cramer finds by</p>

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<p>1 test for interaction the association was</p> <p>2 significantly greater for women who -- and</p> <p>3 then I'm skipping African-American, but I'm</p> <p>4 coming down to -- have a tubal ligation or</p> <p>5 hysterectomy.</p> <p>6 Is that correct?</p> <p>7 A. Yes.</p> <p>8 Q. All right. If talcum powder</p> <p>9 migrates from the perineal region to the</p> <p>10 ovaries, shouldn't exposure to -- exposure to</p> <p>11 talc be far greater in concentration in the</p> <p>12 rectal, vulvar, vaginal, cervical and uterine</p> <p>13 tissues which are closer to the area of</p> <p>14 initial exposure?</p> <p>15 MS. O'DELL: Objection to form.</p> <p>16 A. Well, the acute exposure would</p> <p>17 be greater.</p> <p>18 BY MR. ZELLERS:</p> <p>19 Q. You would expect because the</p> <p>20 acute exposure is greater, that there should</p> <p>21 be inflammation caused in these organs and</p> <p>22 areas, correct?</p> <p>23 A. No. The inflammation and</p> <p>24 oxidative stress is an ongoing process that</p>	<p>1 to talcum powder?</p> <p>2 MS. O'DELL: Object to the</p> <p>3 form.</p> <p>4 A. It doesn't -- it doesn't</p> <p>5 eliminate exposure, but it does remove</p> <p>6 residual exposure, as does sweating, other</p> <p>7 body secretions and so forth.</p> <p>8 BY MR. ZELLERS:</p> <p>9 Q. Are you aware of any studies</p> <p>10 that show inflammation or oxidative stress as</p> <p>11 a result of genital talc use in the rectal,</p> <p>12 vulvar, vaginal, cervical and uterine</p> <p>13 tissues?</p> <p>14 A. No, I'm not.</p> <p>15 Q. Under your theory or belief</p> <p>16 that talcum powder travels from the perineal</p> <p>17 region to the ovaries through the woman's</p> <p>18 reproductive tract, talcum powder must travel</p> <p>19 past the labia, through the vagina, through</p> <p>20 the cervix, and then to the uterus; is that</p> <p>21 right?</p> <p>22 A. That's correct.</p> <p>23 Q. And then the powder travels</p> <p>24 through the uterus and into the fallopian</p>
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<p>1 has to develop over time, and it occurs on a</p> <p>2 chronic basis in areas where foreign bodies</p> <p>3 locate and reside. And talc and talcum</p> <p>4 powder are examples of foreign bodies that</p> <p>5 have the right characteristics to cause</p> <p>6 chemotaxis in reactive oxygen species and</p> <p>7 oxidative status.</p> <p>8 Q. Well, in fact, there would be</p> <p>9 chronic exposure, so if we're dealing with,</p> <p>10 as you described in the very beginning, which</p> <p>11 you were asked, to look at the habitual use</p> <p>12 of talcum powder, that would create exposure</p> <p>13 on a chronic basis to the rectal area and</p> <p>14 tissues, vulvar, vaginal, cervical and</p> <p>15 uterine tissues; is that right?</p> <p>16 MS. O'DELL: Object to the</p> <p>17 form.</p> <p>18 A. I suspect if one doesn't bathe,</p> <p>19 that would be more of an issue, but most</p> <p>20 people bathe regularly as well.</p> <p>21 BY MR. ZELLERS:</p> <p>22 Q. And bathing regularly</p> <p>23 eliminates any exposure in the rectal,</p> <p>24 vulvar, vaginal, cervical and uterine tissues</p>	<p>1 tubes to reach the ovaries; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. On what studies are you relying</p> <p>4 to say that talcum powder affects the body</p> <p>5 differently when it's applied to the perineal</p> <p>6 region and travels to the cervix compared to</p> <p>7 when it is applied directly to the cervix?</p> <p>8 A. I don't think --</p> <p>9 MS. O'DELL: Object to the</p> <p>10 form.</p> <p>11 A. -- there is much of a</p> <p>12 difference.</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. You would expect there to be a</p> <p>15 comparable similar result whether talcum</p> <p>16 powder is applied directly to the cervix</p> <p>17 through the use of dusting of a diaphragm as</p> <p>18 there is to the use of talcum powder in the</p> <p>19 genital areas; is that right?</p> <p>20 A. That is correct. I think the</p> <p>21 two differ probably in terms of quantity very</p> <p>22 significantly. But other than that, they</p> <p>23 would be the same.</p> <p>24 Q. When applied to the perineal</p>

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<p>1 region, talcum powder would also be in close 2 contact with a woman's urethra; is that 3 right? 4 A. Yes. 5 Q. Substances, and in your view, 6 talcum powder, are capable of traveling up 7 the urethra; is that right? 8 MS. O'DELL: Object to the 9 form. 10 A. The urethra has a sphincter 11 which prevents transport beyond that point. 12 BY MR. ZELLERS: 13 Q. Women get urinary tract 14 infections when bacteria travels up the 15 urethra; is that right? 16 A. That's correct. 17 Q. Studies, though, do not show an 18 increase in bladder cancer with talcum powder 19 use; is that right? 20 A. I don't believe that talcum 21 powder transports in any appreciable amount 22 up the urethra into the bladder. 23 Q. Studies do not show an increase 24 in rectal cancer with talcum powder use, do</p>	<p>1 about to reconsider that? 2 A. Because the chatter is that 3 this is something that's on their radar 4 screen currently. 5 Q. What chatter are you aware of? 6 And what is chatter? 7 A. It's discussion among -- within 8 the scientific and healthcare community of 9 things that are on the drawing board for 10 IARC. 11 Q. Do you know whether or not 12 IARC -- well, strike that. 13 IARC has not changed its 14 position that the migration theory and 15 evidence for the migration theory is weak; is 16 that right? 17 MS. O'DELL: Object to the 18 form. 19 A. They have not changed their 20 position that was published in the 2010 21 monograph. 22 BY MR. ZELLERS: 23 Q. All right. You have heard 24 chatter that they may look at it again; is</p>
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<p>1 they? 2 A. No. 3 Q. Are you aware that that IARC -- 4 and you're familiar with IARC, right? 5 A. Yes. 6 Q. Are you aware that IARC rejects 7 this migration theory and calls the evidence 8 weak? 9 MS. O'DELL: Object to the 10 form. 11 A. The IARC has made that 12 statement in their -- I think the 2006 review 13 that resulted in their recent monograph, but 14 I think they're about to reconsider that. 15 BY MR. ZELLERS: 16 Q. Well, they also have stated 17 that in 2010; is that right? 18 A. Well, that's the -- 19 MS. O'DELL: Object to the 20 form. 21 A. That's the monograph from the 22 2006 review. 23 BY MR. ZELLERS: 24 Q. Why do you believe that they're</p>	<p>1 that right? 2 A. Yes. 3 Q. Other than this chatter, you're 4 unaware of any other -- well, strike that. 5 You're unaware of any change in 6 IARC's position with respect to migration, 7 correct? 8 A. Well, an example of what I'm 9 talking about is the Health Canada report, 10 which has contradicted what is found in the 11 IARC monograph and is more current and 12 considers information that will probably go 13 into the next IARC review. 14 MR. ZELLERS: Move to strike as 15 nonresponsive. 16 BY MR. ZELLERS: 17 Q. Does IARC review and rely on 18 draft assessments in formulating their 19 positions? 20 A. IARC relies on primary studies. 21 Q. Not draft assessments, correct? 22 A. Well, the draft assessment that 23 I guess you're referring to, the Health 24 Canada draft assessment, is derived from</p>

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<p style="text-align: right;">Page 206</p> <p>1 primary studies, the same ones that will be 2 considered by IARC. 3 Q. All right. As of today, IARC's 4 published position is that evidence of a 5 migration theory of talcum powder migrating 6 to the ovaries is weak, correct? 7 A. Yes. 8 Q. Have you conducted any tests or 9 experiments with respect to your theory or 10 position that talc migrates to the ovaries 11 through the reproductive tract? 12 A. No, I haven't. 13 Q. How much talc actually reaches 14 the ovaries in your opinion? 15 A. I can't answer that question 16 because the dose has not been quantified. 17 Q. Does it only reach the ovaries 18 during certain times? 19 A. I don't believe so. I think 20 there are many circumstances whereby that 21 migration pathway is functional, and in my 22 belief, the pathway from the perineum to the 23 cervix is pretty much an open channel, and 24 then it continues to be open pretty much all</p>	<p style="text-align: right;">Page 208</p> <p>1 is that right? 2 A. That is correct. 3 Q. You are not one of those 4 physicians, correct? 5 A. I don't claim to be a 6 specialist in gynecology. 7 Q. Your third opinion is that the 8 ovaries lack an intrinsic elimination system; 9 is that right? 10 A. That's correct. 11 Q. Is "intrinsic elimination 12 system" a recognized term of art that's used 13 by gynecologists? 14 A. I don't think so. It was just 15 the term I used to describe the situation. 16 Q. Is "intrinsic elimination 17 system" a term of art used by oncologists? 18 A. The same answer. 19 Q. Have you seen published studies 20 that use that term? 21 A. I don't know. I suspect I 22 could have. It's apparently a small number 23 of ways to describe that in a few words. 24 Q. You do not cite to any studies</p>
<p style="text-align: right;">Page 207</p> <p>1 the way into the pelvic cavity. 2 Q. You are not a specialist in 3 women's health issues, correct? 4 MS. O'DELL: Object to the 5 form. 6 A. Well, I'm a doctor. I've 7 examined a lot of women. 8 BY MR. ZELLERS: 9 Q. Are you -- 10 MS. O'DELL: Excuse me. Are 11 you finished, sir? 12 THE WITNESS: Yes, I'm 13 finished. 14 MS. O'DELL: Okay. 15 BY MR. ZELLERS: 16 Q. Are you an expert in the 17 women's reproductive tract? 18 A. I've taken it apart and put it 19 back together again in medical school, and in 20 other settings I've done OB/GYN rotations. 21 I've participated in pelvic surgeries. I 22 understand the anatomy. 23 Q. There are physicians who are 24 specialists in the female reproductive tract;</p>	<p style="text-align: right;">Page 209</p> <p>1 in the body of your report to support your 2 theory that the ovaries do not have an 3 intrinsic elimination system, correct? 4 A. That's correct. 5 Q. You have not conducted any 6 tests to show that exposure to the ovaries to 7 particulate matter, if any, is longer than 8 exposure to other parts of the female 9 anatomy; is that right? 10 MS. O'DELL: Object to the 11 form. 12 A. I have not conducted any such 13 tests. 14 BY MR. ZELLERS: 15 Q. Is the cervix more or less 16 sensitive to the impact of foreign particles 17 than the ovaries? 18 MS. O'DELL: Object to the 19 form. 20 A. I think that the important 21 point is the residence time that exists, and 22 the cervix is not presented with things for 23 an extended time like the ovaries are in 24 relation to things like talc. But it is</p>

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<p style="text-align: right;">Page 210</p> <p>1 sensitive.</p> <p>2 BY MR. ZELLERS:</p> <p>3 Q. All right. Your fourth</p> <p>4 theory -- or strike that.</p> <p>5 Your fourth opinion is that the</p> <p>6 epidemiological studies show a positive</p> <p>7 relationship between regular perineal</p> <p>8 application of talcum powder and ovarian</p> <p>9 cancer; is that right?</p> <p>10 A. That's correct.</p> <p>11 Q. The studies that you reference</p> <p>12 in this opinion are referred to on pages 6</p> <p>13 and 7 of your report; is that right?</p> <p>14 MS. O'DELL: Object to the</p> <p>15 form.</p> <p>16 A. Most of them, yes.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. You conclude that when</p> <p>19 confounding and bias are exhaustively</p> <p>20 considered -- and do you believe you've done</p> <p>21 that here?</p> <p>22 A. I am restating what authors of</p> <p>23 the primary studies have done. I'm</p> <p>24 evaluating the consistency of the evidence,</p>	<p style="text-align: right;">Page 212</p> <p>1 A. Yes.</p> <p>2 MS. O'DELL: Object to the</p> <p>3 form.</p> <p>4 BY MR. ZELLERS:</p> <p>5 Q. Are you familiar with the term</p> <p>6 "person-years" as it relates to</p> <p>7 epidemiological study?</p> <p>8 A. Yes, I am.</p> <p>9 Q. What is -- strike that.</p> <p>10 How are person-years</p> <p>11 calculated?</p> <p>12 A. They are calculated by -- in</p> <p>13 relation to an exposure or to an existing</p> <p>14 treatment, they're calculated by multiplying</p> <p>15 the duration of the treatment or exposure in</p> <p>16 years by the number of people being studied.</p> <p>17 And that -- the result is person-years.</p> <p>18 Q. Can you explain the difference</p> <p>19 between high-grade serous and low-grade</p> <p>20 serous cancer?</p> <p>21 A. High-grade serous cancer has</p> <p>22 a -- is less differentiated and has a greater</p> <p>23 propensity for metastasis and invasion.</p> <p>24 Q. Are you aware that the</p>
<p style="text-align: right;">Page 211</p> <p>1 not the basic evidence itself.</p> <p>2 Q. The apparent cause and effect</p> <p>3 relationship between perineal talcum powder</p> <p>4 use and ovarian cancer amounts to about a 30%</p> <p>5 increased risk of ovarian cancer in talcum</p> <p>6 powder users.</p> <p>7 Is that your opinion in this</p> <p>8 case?</p> <p>9 A. It is.</p> <p>10 Q. And that is your opinion from</p> <p>11 reviewing the epidemiologic studies that you</p> <p>12 cite in your report?</p> <p>13 A. Yes.</p> <p>14 Q. When epidemiologists refer to</p> <p>15 the statistical power of a study, what are</p> <p>16 they referring to?</p> <p>17 A. Statistical power refers to the</p> <p>18 ability of a study design, if carried out, to</p> <p>19 detect a signal in the data of a particular</p> <p>20 magnitude.</p> <p>21 Q. In plain English, statistical</p> <p>22 power is the likelihood that a study will</p> <p>23 detect an effect when there is an effect to</p> <p>24 be detected; is that fair?</p>	<p style="text-align: right;">Page 213</p> <p>1 epidemiological literature shows that these</p> <p>2 are very different cancers?</p> <p>3 A. They behave quite differently,</p> <p>4 yes.</p> <p>5 Q. Do you know what publication</p> <p>6 bias is?</p> <p>7 A. Yes.</p> <p>8 Q. What is publication bias?</p> <p>9 A. Publication bias is the</p> <p>10 tendency to -- to spin a certain argument</p> <p>11 in -- in order to influence acceptance of</p> <p>12 publications.</p> <p>13 Q. Is that a recognized issue in</p> <p>14 the field of epidemiology, at least as you've</p> <p>15 observed?</p> <p>16 A. It's a -- it's not necessarily</p> <p>17 recognized in the field of epidemiology. It</p> <p>18 exists in all scientific endeavors.</p> <p>19 Q. Is it something that you and</p> <p>20 other physicians and experts and scientists</p> <p>21 need to be aware of?</p> <p>22 A. Yes. I think we're all exposed</p> <p>23 to the effects of that and warned about it as</p> <p>24 we go through our careers.</p>

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<p>1 Q. When I asked you early on what 2 your methodology was, you looked at the 3 published literature, you looked at some 4 websites I think that you told us about 5 earlier, and then you performed a risk 6 assessment and considered whether perineal 7 use of talc products poses a safety risk to 8 consumers; is that right?</p> <p>9 MS. O'DELL: Object to the 10 form.</p> <p>11 A. Well, that's a gross 12 oversimplification of the risk assessment 13 process that I performed.</p> <p>14 The review of the literature, 15 which was based on the question that I was 16 asked to address, was a fairly exhaustive one 17 which incorporated a search for every 18 pertinent publication that was available and 19 included multiple languages.</p> <p>20 It then was -- proceeded into a 21 distillation of the facts that were -- that 22 were claimed based on those individual 23 studies and investigations, and a comparison 24 of those, one with another, eventually</p>	<p>1 been published as well. And I felt that was 2 sufficient to be able to produce this report 3 that addressed the question I was asked.</p> <p>4 Q. As you told us earlier, you 5 have never published a meta-analysis on any 6 topic; is that right?</p> <p>7 A. That's correct.</p> <p>8 Q. You cite to some of the 9 available studies on talcum powder use in 10 ovarian cancer, but not to all of the 11 studies, correct?</p> <p>12 MS. O'DELL: Object to the 13 form.</p> <p>14 A. That's true.</p> <p>15 BY MR. ZELLERS:</p> <p>16 Q. What was your reasoning for 17 focusing on certain studies and excluding 18 other studies?</p> <p>19 A. The studies that I referenced 20 were those that had specific aspects that 21 directly influenced my report or my 22 conclusions or that I felt were illustrative 23 of comments I was making in the report, and 24 that's why they were referenced.</p>
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<p>1 considering them all as a whole to arrive at 2 conclusions that addressed the question.</p> <p>3 BY MR. ZELLERS:</p> <p>4 Q. That was your methodology; is 5 that right?</p> <p>6 A. That is the methodology, yes.</p> <p>7 Q. Did you consider the Bradford 8 Hill criteria or factors in reaching your 9 conclusions and opinions in this matter?</p> <p>10 A. That's part of the methodology 11 which is outlined in my report.</p> <p>12 Q. In analyzing the Bradford Hill 13 criteria, did you conduct a meta-analysis of 14 the available data to reach a conclusion 15 about the relative risk?</p> <p>16 A. No, I did not.</p> <p>17 Q. Why didn't you conduct a 18 meta-analysis for this case?</p> <p>19 A. I did not have the time to do a 20 meta-analysis in this case, first of all. 21 Secondly, there have been a number of other 22 meta-analyses performed, and I had those 23 results available to me in addition to 24 various reviews of the literature that have</p>	<p>1 All of the studies may not have 2 risen to that -- the level of requiring being 3 referenced, but pretty much all the studies 4 are included in the literature that I 5 reviewed.</p> <p>6 Q. You cite in the report the 7 studies that were favorable or supportive of 8 your opinions, correct?</p> <p>9 A. Well, I cited a number of 10 studies, not all of which were favorable to 11 my overall opinions, at least not on the 12 surface.</p> <p>13 Q. Did you cite all of the studies 14 that you believe in one way or another 15 support your opinions in this case?</p> <p>16 A. I don't think so.</p> <p>17 Q. You believe there are 18 additional studies that support your opinions 19 that you did not cite?</p> <p>20 A. They're in the literature list.</p> <p>21 Q. Did you cite the opinions that 22 refuted -- strike that.</p> <p>23 Did you cite the studies that 24 refuted your opinions in this matter?</p>

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<p>1 A. I cited some studies that had 2 opinions that -- or that had conclusions that 3 did not necessarily agree with mine, but I 4 don't think they refuted my conclusions. 5 Q. Do you believe the standard for 6 proving causation in the scientific 7 literature is the same one that applies in 8 this litigation? 9 MS. O'DELL: Object to the 10 form. 11 A. I don't know that. 12 BY MR. ZELLERS: 13 Q. A document you brought here 14 today was an FDA letter? 15 A. Yeah, I think you marked it. 16 Q. I did mark it. Why don't you 17 see if you could find it so I can ask you a 18 couple of questions about it. 19 A. There it is. That one? 20 Q. Yes. Exhibit 10 is an FDA 21 letter dated April 1st of 2014 to a 22 Dr. Epstein; is that right? 23 A. Yes. 24 Q. That is a document that you</p>	<p>1 more detail to be able to answer that 2 specifically. 3 Q. Well, essentially, based upon 4 its analysis as of 2014, the FDA concluded 5 that causation had not been established as 6 between genital talcum powder use and ovarian 7 cancer or an increased risk of ovarian 8 cancer, correct? 9 A. Well, it said that an updated 10 review failed to identify any new compelling 11 literature data or new scientific evidence. 12 I don't think they indicate here that they 13 actually did a standard review of that 14 literature. 15 Q. Well, take a look, if you will, 16 at page 4. The FDA sets forth its 17 epidemiology and etiology findings; is that 18 right? 19 A. Yes. 20 Q. The FDA has a number of very 21 capable physicians, scientists, 22 toxicologists, pharmacologists and medical 23 professionals; is that right? 24 MS. O'DELL: Object to the</p>
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<p>1 reviewed and considered as part of your 2 analysis of this case; is that right? 3 A. Yes. 4 Q. Do you believe that that 5 exhibit, Exhibit 10, is supportive of your 6 opinions in this matter? 7 A. I don't think it's very 8 supportive. It's -- it's in response to a 9 proposal from a citizens voluntary agency to 10 provide more stringent labeling on talcum 11 powder products, and the agency rejected 12 the -- that petition. 13 Q. The FDA is the regulatory body 14 in the United States that oversees food, drug 15 and cosmetics; is that right? 16 MS. O'DELL: Object to the 17 form. 18 A. Yes. 19 BY MR. ZELLERS: 20 Q. This letter -- strike that. 21 In this letter the FDA goes 22 through and analyzes some of the Bradford 23 Hill factors; is that right? 24 A. I'd have to look at this in</p>	<p>1 form. 2 A. I don't know if they're still 3 working, but they have good people on staff. 4 BY MR. ZELLERS: 5 Q. And just so, a year or two or 6 three, if this transcript is ever reviewed, 7 we are in the midst of a shutdown of at least 8 portions of the government; is that right? 9 A. That's correct. 10 Q. And that is what your comment 11 was directed to, correct? 12 A. That is correct. 13 Q. On page 4 the FDA states: 14 After consideration of the scientific 15 literature submitted in support of both 16 citizens' petitions, FDA found. 17 And then, number 2, that 18 several of the studies acknowledge biases in 19 the study design and no single study has 20 considered all the factors that potentially 21 contribute to ovarian cancer, including 22 selection bias and/or uncontrolled 23 confounding that result in spurious positive 24 associations between talc use and ovarian</p>

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<p>1 cancer risk. 2 Did I read that correctly? 3 A. You did read it correctly. 4 Q. Does that appear to be at least 5 one of the conclusions of the FDA after 6 considering the scientific literature as of 7 early 2014? 8 MS. O'DELL: Object to the 9 form. 10 A. Yes, that is listed as an FDI 11 finding -- FDA finding. 12 BY MR. ZELLERS: 13 Q. The FDA noted that a 14 dose-response -- strike that. 15 The FDA noted that 16 dose-response evidence is lacking; is that 17 right? 18 A. A dose-response -- 19 Q. Two things. The FDA notes that 20 there's a lack of consistency in the study 21 results, correct? 22 MS. O'DELL: Where are you 23 reading? I'm sorry. 24 MR. ZELLERS: I'm looking at</p>	<p>1 form. 2 A. That is correct. 3 BY MR. ZELLERS: 4 Q. You are a paid expert for the 5 plaintiffs in this litigation; is that right? 6 A. That is correct. 7 Q. To your knowledge, the FDA is 8 not paid -- well, let me withdraw that. 9 A. I wouldn't go out on a limb 10 there. 11 Q. Number 4, Conclusion 4, a 12 cogent biological mechanism by which talc 13 might lead to ovarian cancer is lacking. 14 Exposure to talc does not account for all 15 cases of ovarian cancer and there was no 16 scientific consensus on the proportion of 17 ovarian cancer cases that may be caused by 18 talc exposure. 19 Was that a conclusion of the 20 FDA based upon its review of the 21 epidemiologic literature? 22 MS. O'DELL: Object to the 23 form. 24 A. Yes, it was, and it's one that</p>
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<p>1 Conclusion 3. 2 THE WITNESS: Point 3. 3 A. They found that the 4 case-control studies did not demonstrate a 5 consistent positive association across 6 studies; although some studies have found 7 small positive associations between talc and 8 ovarian cancer, but lower confidence limits 9 are often close to 1, and dose-response 10 evidence is lacking. 11 BY MR. ZELLERS: 12 Q. That was FDA's conclusion 13 number 3 based upon its review of the 14 scientific literature; is that right? 15 MS. O'DELL: Object to the 16 form. 17 A. It's correct. It's not a valid 18 interpretation of the statistical results, 19 but that was one of their findings. 20 BY MR. ZELLERS: 21 Q. Well, that was their finding. 22 You disagree at least in part with their 23 finding; is that right? 24 MS. O'DELL: Object to the</p>	<p>1 I also disagree with. 2 BY MR. ZELLERS: 3 Q. IARC also considered the 4 Bradford Hill considerations; is that right? 5 A. Yes, it did. 6 Q. IARC rejected classification of 7 talc as a carcinogenic, instead assigning it 8 to the classification of possibly 9 carcinogenic to humans; is that correct? 10 A. That's correct. 11 Q. We've already discussed the 12 IARC categories briefly, but let's mark a 13 document from the IARC website as to the 14 classifications, Exhibit 21. 15 (Carson Deposition Exhibit 21 16 marked.) 17 BY MR. ZELLERS: 18 Q. Tell me if you recognize that. 19 A. Yes. 20 Q. Exhibit 21 is from the IARC 21 website, and it goes through the 22 classifications of different agents that have 23 been made by the International Agency for 24 Research on Cancer; is that right?</p>

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<p style="text-align: right;">Page 226</p> <p>1 A. Yes, that's correct.</p> <p>2 Q. It has studied and included 120</p> <p>3 agents in the Group 1 category, which is</p> <p>4 carcinogenic to humans, correct?</p> <p>5 A. That's correct.</p> <p>6 Q. That's the only category in</p> <p>7 which IARC finds sufficient evidence in</p> <p>8 humans, correct?</p> <p>9 MS. O'DELL: Object to the</p> <p>10 form.</p> <p>11 A. That's the category that</p> <p>12 represents substances for which there is</p> <p>13 sufficient and irrefutable evidence of human</p> <p>14 carcinogenesis.</p> <p>15 BY MR. ZELLERS:</p> <p>16 Q. It lists 82 agents in Group 2A</p> <p>17 as being probably carcinogenic to humans; is</p> <p>18 that right?</p> <p>19 A. That's correct.</p> <p>20 Q. IARC is certainly willing to</p> <p>21 declare agents as either a known or probable</p> <p>22 carcinogen; is that right?</p> <p>23 A. That's correct.</p> <p>24 Q. There is only one agent in</p>	<p style="text-align: right;">Page 228</p> <p>1 MS. O'DELL: Object to the</p> <p>2 form.</p> <p>3 A. I think limited evidence also</p> <p>4 refers to just the number of studies that</p> <p>5 have been performed as well as the quality of</p> <p>6 the studies.</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. Well, based upon the evidence</p> <p>9 that is available, the studies that are</p> <p>10 available, a 2B designation by IARC means</p> <p>11 that IARC cannot rule out chance, bias or</p> <p>12 confounding with reasonable confidence,</p> <p>13 correct?</p> <p>14 MS. O'DELL: Objection, asked</p> <p>15 and answered.</p> <p>16 A. Not always the case.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. That's part of the definition,</p> <p>19 isn't it?</p> <p>20 A. I don't believe it applies to</p> <p>21 every agent or every evaluation.</p> <p>22 Q. Well, I'll not take the time to</p> <p>23 go through the IARC definitions; if we at the</p> <p>24 end of the day have extra time, we'll go back</p>
<p style="text-align: right;">Page 227</p> <p>1 Group 4, probably not carcinogenic to humans,</p> <p>2 correct?</p> <p>3 A. Yes. I thought that number had</p> <p>4 gone up recently, but the date here is</p> <p>5 November 2018, so some may have been moved</p> <p>6 back into Group 3.</p> <p>7 Q. So out of the over 1,000 agents</p> <p>8 that IARC has reviewed, it's only placed one</p> <p>9 agent in the Group 4 category, probably not</p> <p>10 carcinogenic; is that right?</p> <p>11 A. That's correct.</p> <p>12 Q. There is no Group 5, not</p> <p>13 carcinogenic; is that right?</p> <p>14 A. That's correct.</p> <p>15 Q. With genital talc, IARC</p> <p>16 Group 2B designation -- well, strike that.</p> <p>17 Genital talc is listed as an</p> <p>18 IARC Group 2B designated substance; is that</p> <p>19 right?</p> <p>20 A. That's correct.</p> <p>21 Q. That's based on limited</p> <p>22 evidence in humans, which means that IARC</p> <p>23 cannot rule out chance, bias or confounding</p> <p>24 with reasonable confidence, correct?</p>	<p style="text-align: right;">Page 229</p> <p>1 and we'll take a look.</p> <p>2 What else is in the Class 2B,</p> <p>3 possibly carcinogenic. Ginkgo biloba, is</p> <p>4 that something you're aware of that's in that</p> <p>5 category?</p> <p>6 MS. O'DELL: Object to the</p> <p>7 form.</p> <p>8 A. That's a biological material.</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. Pickled vegetables?</p> <p>11 A. That may be in Group 2B.</p> <p>12 Q. Occupational carpentry and</p> <p>13 joinery?</p> <p>14 MS. O'DELL: Objection to form.</p> <p>15 A. That's wood dust exposure.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. Also 2B; is that right?</p> <p>18 A. Wood dust itself is Group 1.</p> <p>19 The occupation is Group 2B.</p> <p>20 Q. Let me ask you about some</p> <p>21 individual Bradford Hill criteria. On</p> <p>22 page 10 of your report, you state that you</p> <p>23 gave the most weight to strength of</p> <p>24 association, consistency and biologic</p>

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<p>1 plausibility; is that right?</p> <p>2 A. That's correct.</p> <p>3 Q. How much weight did you give to</p> <p>4 the other six factors?</p> <p>5 A. Sufficient.</p> <p>6 Q. Why did you put less weight on</p> <p>7 those?</p> <p>8 A. Because the strength of</p> <p>9 association, the consistency of the evidence</p> <p>10 and the biological plausibility of perineal</p> <p>11 talc, talcum powder application as</p> <p>12 responsible for the occurrence of ovarian</p> <p>13 cancer was compelling.</p> <p>14 Q. FDA focused on dose, correct?</p> <p>15 A. Yes.</p> <p>16 Q. You did not; is that right?</p> <p>17 A. That's right.</p> <p>18 Q. The first Bradford Hill factor</p> <p>19 that you focused on was strength of</p> <p>20 association.</p> <p>21 What association does the</p> <p>22 literature report between talc use and</p> <p>23 ovarian cancer?</p> <p>24 A. Overall, evaluating the</p>	<p>1 been failed attempts, but they have been</p> <p>2 attempts to estimate the quantity of powder</p> <p>3 that you start with and the amount that</p> <p>4 results in the application to the perineum by</p> <p>5 using models and actually doing some</p> <p>6 measurements and recording activities.</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. You did not do any modeling or</p> <p>9 any assessment of the quantity of baby powder</p> <p>10 that was involved with daily use; is that</p> <p>11 right?</p> <p>12 A. No, I relied on those others.</p> <p>13 Q. When you say 30% increased</p> <p>14 risk, that's a 1.3 odds ratio; is that right?</p> <p>15 A. That's correct.</p> <p>16 Q. And that comes largely from the</p> <p>17 case-control studies, correct?</p> <p>18 MS. O'DELL: Object to the</p> <p>19 form.</p> <p>20 A. Yes, but it's also consistent</p> <p>21 with some of the information from the cohort</p> <p>22 studies.</p> <p>23 BY MR. ZELLERS:</p> <p>24 Q. Epidemiologists consider a 1.3</p>
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<p>1 universe of research, epidemiologic research</p> <p>2 that's been done on this, it shows an average</p> <p>3 30% increase in ovarian cancer risk for those</p> <p>4 who regularly apply talcum powder to the</p> <p>5 perineum.</p> <p>6 Q. Regular application of talcum</p> <p>7 powder means what?</p> <p>8 A. It -- I believe that it means</p> <p>9 daily or thereabouts.</p> <p>10 Q. In what form of application?</p> <p>11 A. Talcum powder.</p> <p>12 Q. In what amount?</p> <p>13 A. Whatever is necessary or</p> <p>14 desired by the user.</p> <p>15 Q. Does that vary from woman to</p> <p>16 woman?</p> <p>17 A. It does.</p> <p>18 Q. Did you make any attempt to</p> <p>19 assess what regular use of talcum powder was?</p> <p>20 MS. O'DELL: Object to the</p> <p>21 form.</p> <p>22 A. There have been a couple of</p> <p>23 attempts to try to quantify what -- what that</p> <p>24 means. I think for the most part they've</p>	<p>1 odds ratio in a case-control study to be a</p> <p>2 weak or modest association; is that right?</p> <p>3 MS. O'DELL: Object to the</p> <p>4 form.</p> <p>5 A. That's correct.</p> <p>6 BY MR. ZELLERS:</p> <p>7 Q. Where here we're talking only</p> <p>8 about statistical associations, not</p> <p>9 causation, correct?</p> <p>10 MS. O'DELL: Object to the</p> <p>11 form.</p> <p>12 A. Well, association eventually</p> <p>13 becomes causation when the -- when the</p> <p>14 evidence mounts to a point where it becomes</p> <p>15 recognized by all of the players that this is</p> <p>16 what's going on.</p> <p>17 A 30% increase may be</p> <p>18 classified by epidemiologists as weak or</p> <p>19 modest, but if you look at the number of</p> <p>20 women in this country who die each year from</p> <p>21 this fatal disease, that represents about</p> <p>22 3,000 lives that could potentially be saved</p> <p>23 through prevention.</p> <p>24 Q. There is not a --</p>

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<p>1 MS. BOCKUS: Excuse me, I need 2 to object as nonresponsive. 3 MR. ZELLERS: Yes, join. 4 BY MR. ZELLERS: 5 Q. There is not a consensus at 6 this time with respect to any causation 7 relating to genital talc and ovarian cancer, 8 is there? 9 MS. O'DELL: Objection to the 10 form. 11 A. I believe that that consensus 12 is building. 13 BY MR. ZELLERS: 14 Q. FDA -- that's not FDA's 15 position, correct? 16 MS. O'DELL: Object to the 17 form. 18 A. Not at the moment. 19 BY MR. ZELLERS: 20 Q. That's not the position of the 21 National Cancer Institute; is that right? 22 A. That's correct. 23 Q. That's not the position of the 24 CDC; is that correct?</p>	<p>1 epidemiologists are concerned, correct? 2 MS. O'DELL: Object to -- 3 object to the form. 4 A. It's an increased risk that 5 translates into human lives, so it depends on 6 your point of view. 7 MS. BOCKUS: Object to form -- 8 I mean, sorry, nonresponsive, move to 9 strike. 10 MR. ZELLERS: Join. 11 MS. O'DELL: Oppose. 12 DR. THOMPSON: Agreed. 13 BY MR. ZELLERS: 14 Q. The 1.3 relative risk that you 15 believe generally applies, that would relate 16 to epithelial cancers; is that right? 17 A. Yes. 18 Q. That's what you're limiting 19 your opinions to in this case, correct? 20 MS. O'DELL: Object to the 21 form. 22 A. Well, these opinions relate to 23 several of the cancers that have shown 24 increases in these background epidemiologic</p>
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<p>1 A. That's correct. 2 Q. IARC does not refer to any 3 association between perineal talc use and 4 ovarian cancer as a strong association, does 5 it? 6 MS. O'DELL: Object to the 7 form. 8 A. It calls it a Group 2B 9 carcinogen, which is fairly significant. 10 BY MR. ZELLERS: 11 Q. Well, we discussed a few 12 minutes ago that if an agent is a Group 2B 13 carcinogen, that is based on limited evidence 14 in humans; is that right? 15 A. That's correct. 16 Q. All right. Your opinions on 17 strength of association, do they apply 18 equally to all forms of ovarian cancer? 19 A. No, they don't. These apply to 20 the epithelial ovarian cancer spectrum. 21 Q. Your opinions in terms of there 22 being a -- well, let me withdraw that. 23 We've agreed that 1.3 is not a 24 strong association, at least insofar as</p>	<p>1 studies, which include the epithelial ovarian 2 cancers, including the serous; the borderline 3 cancers are also showing increases in some of 4 the studies. So it's the group of those 5 cancers, yes. 6 BY MR. ZELLERS: 7 Q. The cohort studies, prospective 8 cohort studies, have not shown an association 9 between talc and ovarian cancer, correct? 10 MS. O'DELL: Object to the 11 form. 12 A. They have in some subtypes. 13 BY MR. ZELLERS: 14 Q. There was an initial 15 description with respect to the first Nurses' 16 study that was not supported in the update of 17 that study; is that correct? 18 A. The Nurses' Health Study? 19 Q. Yes. 20 A. Yes, that's correct. 21 Q. Let's look at a different 22 criteria, consistency. The literature does 23 not show a consistent association between 24 talc use and ovarian cancer, correct?</p>

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<p>1 MS. O'DELL: Object to the 2 form. 3 A. I believe that, in fact, 4 research shows -- does show a consistent 5 pattern. 6 BY MR. ZELLERS: 7 Q. The cohort studies do not show 8 an association between talc use and ovarian 9 cancer as we just discussed, correct? 10 A. The basic cohort studies that 11 look at all of the subjects and all of the 12 cancers together typically do not rise to the 13 level of significance. 14 Q. The hospital-based case-control 15 studies collectively do not show an 16 association between talc use and ovarian 17 cancer, correct? 18 A. I sort of discount the 19 distinction between the hospital-based 20 studies and the community-based studies. I'm 21 not sure whether there are valid reasons to 22 consider those differently. 23 Q. We've discussed earlier that 24 you are not an epidemiologist; is that right?</p>	<p>1 ill patients in the community to healthy 2 people in the community, correct? 3 A. In some cases that might be 4 correct, but I'm not sure that's any -- in 5 any sort of world an advantage. 6 Q. Well, shouldn't there be 7 consistency if the Bradford Hill criteria is 8 to be -- well, strike that. 9 In applying the Bradford Hill 10 criteria of consistency, there should be 11 consistency across different types of 12 studies, cohort studies, hospital-based 13 case-control studies, and population-based 14 case-control studies, correct? 15 MS. O'DELL: Object to the 16 form. 17 A. That's correct. 18 BY MR. ZELLERS: 19 Q. Isn't the absence of an 20 association in the cohort studies especially 21 significant in that the study design for the 22 cohort studies reduces the likelihood of 23 recall bias? 24 A. There are many forms of bias</p>
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<p>1 MS. O'DELL: Object to the 2 form, misstates his testimony. 3 A. I don't think I necessarily 4 agreed to that characterization because I 5 deal a lot with epidemiologic work. I'm a 6 faculty member in the Department of 7 Epidemiology at the University of Texas 8 School of Public Health, and some may 9 consider me an epidemiologist. 10 BY MR. ZELLERS: 11 Q. Do you consider yourself an 12 expert in epidemiology? 13 A. No. 14 Q. Do you agree -- well, do you 15 agree that hospital-based case-control 16 studies are less susceptible to selection 17 bias than population-based case-control 18 studies? 19 A. It depends on the methodology 20 that's used to recruit the study subjects. 21 Q. With hospital-based 22 case-controlled studies, you're more likely 23 to be comparing hospitalized patients to 24 hospitalized patients rather than comparing</p>	<p>1 that study designers need to consider in the 2 process of designing a study, and there are 3 even more types of bias that are discovered 4 after a study has begun. 5 You can fault case-control 6 studies for being particularly sensitive to 7 recall bias, but many of these authors who 8 perform these studies indicated that they 9 were well aware of that bias potential and 10 took measures to avoid it. 11 The same thing can be said 12 about cohort studies. They suffer from other 13 forms of bias, misclassification in 14 particular. They may also suffer from the 15 fact that they are extremely expensive, have 16 long duration, and require very large numbers 17 of subjects in order to carry them out and 18 are frequently underpowered and unable to 19 arrive at the conclusions that they seek for 20 that reason. 21 MR. ZELLERS: Move to strike as 22 nonresponsive. 23 BY MR. ZELLERS: 24 Q. Is it possible that recall bias</p>

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<p style="text-align: right;">Page 242</p> <p>1 explains the difference between the cohort 2 studies and the retrospective case-control 3 studies? 4 MS. O'DELL: Object to form, 5 asked and answered. 6 A. I don't believe that that is 7 the case. 8 BY MR. ZELLERS: 9 Q. Is it possible? 10 MS. O'DELL: Objection. 11 A. Theoretically it would be 12 possible. 13 BY MR. ZELLERS: 14 Q. Are you familiar with the 15 Berge -- Berge 2017 study? 16 A. Yes. 17 Q. Is that a study that you cite 18 and reviewed and rely on? 19 A. It was a meta-analysis. 20 Q. Is that a meta-analysis that 21 you cite, review and have relied upon? 22 A. Yes. 23 Q. Take a look, if you will, at 24 Exhibit 22.</p>	<p style="text-align: right;">Page 244</p> <p>1 paragraph. Reading from the second full 2 paragraph, the authors discuss the fact that 3 the association between genital talc use and 4 risk of ovarian cancer is present in 5 case-control but not in cohort studies, can 6 be attributed to bias in the former type of 7 studies; is that right? 8 MS. O'DELL: Object to the 9 form. 10 A. That's what it says. 11 BY MR. ZELLERS: 12 Q. Then continuing down: 13 Information bias from retrospective 14 self-report of talc use is a possible 15 explanation for the association detected in 16 case-control studies. 17 Is that right? 18 A. That's what it says. 19 Q. What was your methodology for 20 discounting the effect of recall bias in the 21 population-based case-control studies? 22 A. The fact that several authors 23 discussed the possibility of recall bias and 24 incorporated methodology for avoiding recall</p>
<p style="text-align: right;">Page 243</p> <p>1 (Carson Deposition Exhibit 22 2 marked.) 3 THE WITNESS: Thank you. 4 MS. O'DELL: Thank you. 5 BY MR. ZELLERS: 6 Q. You're familiar with this 7 meta-analysis; is that right? 8 A. Yes. 9 Q. The authors conclude that 10 information bias from retrospective 11 self-report of talc use is a possible 12 explanation for the association detected in 13 case-control studies; is that right? 14 MS. O'DELL: I'm sorry, are you 15 reading from a certain page? 16 MR. ZELLERS: I am. 17 MS. O'DELL: Can you direct it 18 to us, please? 19 THE WITNESS: Could you tell us 20 where that is? 21 MR. ZELLERS: Sure. 22 BY MR. ZELLERS: 23 Q. Take a look if you will on 24 page 6, the right-hand column, third</p>	<p style="text-align: right;">Page 245</p> <p>1 bias, for example, placing parallel questions 2 that should be affected in the same way, and 3 still showed a positive result for talc and 4 ovarian cancer is one reason. 5 The other has to do with 6 consistency of the results, and although 7 you've stated that from these various 8 documents, including this quotation, that the 9 case-control studies showed positive 10 associations but the cohort studies did not, 11 I would -- I would refute that by saying that 12 all of the -- the vast majority of all of the 13 studies show a positive odds ratio or 14 relative risk, even if they don't rise to the 15 level of significance. 16 If these results were obtained 17 simply by chance, you would expect an equal 18 number of positive results and negative 19 results, but we don't have that here. We 20 have practically all positive results with 21 three or four outliers. 22 And so -- 23 Q. We looked at the Taher paper 24 early on in this deposition where Taher</p>

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<p>1 concluded that 15 out of the 30 case-control 2 studies reported a statistically significant 3 association between genital talc use and 4 ovarian cancer, correct? 5 A. That's correct, but you're 6 not -- you're not talking about the other 15. 7 Q. The hospital-based case-control 8 studies collectively do not show a 9 statistically significant association between 10 talc use and ovarian cancer, correct? 11 MS. O'DELL: Object to the 12 form. 13 A. I don't know that that is the 14 case. 15 BY MR. ZELLERS: 16 Q. You don't know that it's not 17 the case; you'd have to go back and relook at 18 the studies, fair? 19 A. I'd have to look through here, 20 which I'm happy to do if you want me to, but 21 I don't believe that that's the case. 22 Q. In fact, the author, you cite 23 the Langseth paper, a 2008 paper, as 24 supportive of your position; is that right?</p>	<p>1 page. 2 MS. O'DELL: Object to the 3 form. 4 BY MR. ZELLERS: 5 Q. Is that the conclusion of the 6 authors? 7 A. What I'm reading here is on 8 balance, the epidemiological evidence 9 suggests that the use of cosmetic talc in the 10 perineal area may be associated with ovarian 11 cancer risk. The mechanism of 12 carcinogenicity may be related to 13 inflammation. 14 Q. Take a look at the paragraph on 15 the right-hand side under Proposal to 16 Research Community. I'm looking at the 17 second page of the Langseth article. 18 Are you there? 19 A. Yes, I am. 20 Q. The authors state: The current 21 body of experimental and epidemiological 22 evidence is insufficient to establish a 23 causal association between perineal use of 24 talc and ovarian cancer risk.</p>
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<p>1 A. Yes. 2 Q. I'll mark that 3 Deposition Exhibit 23. 4 A. I think it was 2004, was it 5 not? 6 Q. Well, I'm going to hand it to 7 you and we can look at it together. 8 (Carson Deposition Exhibit 23 9 marked.) 10 A. Okay. 11 BY MR. ZELLERS: 12 Q. You're familiar with the 13 Langseth paper; is that right? 14 A. Yes. 15 (Comments off the stenographic 16 record.) 17 BY MR. ZELLERS: 18 Q. Langseth and the authors 19 concluded that the current body of 20 experimental and epidemiological evidence is 21 insufficient to establish a causal 22 association between perineal use of talc and 23 ovarian cancer risk; is that right? 24 And I'm looking at the second</p>	<p>1 Is that right? 2 MS. O'DELL: Object to the 3 form. 4 A. That's what it says. 5 BY MR. ZELLERS: 6 Q. Experimental research is needed 7 to better characterize deposition, retention 8 and clearance of talc to evaluate the ovarian 9 carcinogenicity of talc. 10 Is that what the authors state? 11 A. Well, that's what it says, but 12 it says much more. In fact, the editors of 13 the journal, in the section on the next page 14 that is titled What This Study Adds, say: 15 Epidemiological evidence suggests that the 16 use of cosmetic talc in the perineal area may 17 be associated with ovarian cancer risk. The 18 IARC has classified this use of talc as 19 possibly carcinogenic to human beings, 20 Group 2B. The mechanism of carcinogenicity 21 may be related to inflammation. This paper 22 focused on the high degree of consistency in 23 the studies accomplished so far and what 24 should be the focus in future studies.</p>

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<p>1 So I --</p> <p>2 Q. And then the conclusion is what</p> <p>3 I read, that: The current body of</p> <p>4 experimental and epidemiological evidence is</p> <p>5 insufficient to establish a causal</p> <p>6 association between perineal use of talc and</p> <p>7 ovarian cancer risk.</p> <p>8 Correct?</p> <p>9 MS. O'DELL: Object to the</p> <p>10 form.</p> <p>11 A. That is what it says, but this</p> <p>12 was accepted in 2007, which was now 12 years</p> <p>13 ago.</p> <p>14 BY MR. ZELLERS:</p> <p>15 Q. Let me ask you about the cohort</p> <p>16 studies. They involved a much greater number</p> <p>17 of women than the case-controlled studies; is</p> <p>18 that right?</p> <p>19 MS. O'DELL: Object to the</p> <p>20 form.</p> <p>21 A. Well, they did not involve more</p> <p>22 cases, but they involved more women because</p> <p>23 in order to do a cohort study, you have to</p> <p>24 start with a huge group of people and wait</p>	<p>1 doesn't happen.</p> <p>2 Q. Is it your testimony that the</p> <p>3 cohort studies relating to genital talc use</p> <p>4 and ovarian cancer are spinning the roulette</p> <p>5 wheel?</p> <p>6 MS. O'DELL: Object to the</p> <p>7 form.</p> <p>8 A. In terms of the power of the</p> <p>9 studies to detect a meaningful difference</p> <p>10 among the subjects, yes.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. That's your testimony as an</p> <p>13 expert in this case; is that right?</p> <p>14 A. It is my testimony that cohort</p> <p>15 studies, including these, are chronic -- or</p> <p>16 quite often underpowered simply because of</p> <p>17 the expense associated with performing these</p> <p>18 studies.</p> <p>19 Q. What analysis did you do to</p> <p>20 conclude that the cohort studies in this</p> <p>21 area, the four cohort studies, are</p> <p>22 underpowered?</p> <p>23 A. Like I just mentioned to you, I</p> <p>24 read the studies and looked at their</p>
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<p>1 for them to develop cancers, and then count</p> <p>2 those cancers.</p> <p>3 BY MR. ZELLERS:</p> <p>4 Q. What was your methodology for</p> <p>5 weighing the power of the cohort studies</p> <p>6 versus the case-control studies?</p> <p>7 A. The cohort studies, it wasn't</p> <p>8 apparent in every research report exactly how</p> <p>9 they had done their sample size calculations</p> <p>10 and power determinations, but in many cases</p> <p>11 the lack of arriving at conclusions was</p> <p>12 simply due to an inability to detect an</p> <p>13 effect in the cohort studies, not that they</p> <p>14 detected that there was not an effect. And</p> <p>15 that's unfortunately a disadvantage of an</p> <p>16 underpowered study.</p> <p>17 Q. Is it your testimony that the</p> <p>18 cohort studies are underpowered?</p> <p>19 A. I think by and large most</p> <p>20 cohort studies are underpowered and --</p> <p>21 because power calculations are based on</p> <p>22 chance. Investigators are sort of spinning</p> <p>23 the roulette wheel and hoping that the number</p> <p>24 that they want comes up. In some cases that</p>	<p>1 conclusions, and their conclusions were not</p> <p>2 that the effect didn't exist, but they</p> <p>3 couldn't detect it.</p> <p>4 MR. ZELLERS: Let's go off the</p> <p>5 record because we need to change our</p> <p>6 tape.</p> <p>7 THE VIDEOGRAPHER: We're off</p> <p>8 the record at 3:06, end of Tape 3.</p> <p>9 (Recess taken, 3:06 p.m. to</p> <p>10 3:19 p.m.)</p> <p>11 THE VIDEOGRAPHER: We're on the</p> <p>12 record at 3:19, beginning of Tape 4.</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. Dr. Carson, you are not a</p> <p>15 statistician, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. You are not a biostatistician;</p> <p>18 is that right?</p> <p>19 A. That's right.</p> <p>20 Q. Do you agree that some of the</p> <p>21 case-control studies have shown statistically</p> <p>22 significant findings and others have not?</p> <p>23 A. I do agree that.</p> <p>24 Q. If a study does not show a</p>

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<p>1 statistically significant association, it 2 could mean that no risk exists, as we've 3 discussed; is that right? 4 A. That's correct. 5 Q. What methodology did you use to 6 weigh the lack of statistical significance 7 across studies? 8 MS. O'DELL: Object to the 9 form. 10 A. Across all of the case-control 11 studies? 12 BY MR. ZELLERS: 13 Q. Yes. 14 A. I simply treated them as 15 isolated research designs that were done on 16 different populations in different places 17 with different considerations. They were not 18 necessarily comparable, like apples to apples 19 or oranges to oranges; they were very 20 different studies in most cases, and so I 21 felt it was important to allow their findings 22 to stand on their own. 23 Q. I want to talk to you about 24 dose-response. That's another of the</p>	<p>1 front of you? 2 A. I do. 3 I would also add that the 4 Penninkilampi meta-analysis also found a 5 dose-response. 6 Q. Do you mention Penninkilampi at 7 all in your report? 8 A. It's cited. 9 Q. In the body of your report? 10 A. I think it's in there 11 somewhere. 12 Q. You believe it is; is that 13 right? 14 A. I do. 15 Q. Well, I'll ask you a couple of 16 questions about it then. 17 Before I do, let's talk a 18 little bit more about your report. So go to 19 page 7. You state at the very top of that 20 page that it has been difficult to estimate 21 dose in order to evaluate the dose-response 22 relationship for ovarian cancer; is that 23 right? 24 A. That's correct.</p>
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<p>1 Bradford Hill criteria; is that right? 2 A. That's correct. 3 Q. Which studies show a 4 dose-response, talc exposure and ovarian 5 cancer? 6 A. Let me see here. I'm looking 7 at my notes. The Harlow study from 1992 8 showed a dose-response, and the Cramer 2016 9 study showed a dose trend with strong odds 10 ratios for premenopausal women and hormone 11 therapy-treated women with greater than 12 24 years of exposure. 13 The Schildkraut study, also a 14 case-controlled study of 2016, showed a 15 dose-response. 16 Q. There are a number of studies 17 that did not show a dose-response; is that 18 right? 19 A. It's correct. They did not 20 necessarily show there was not a 21 dose-response. They just, as I was 22 mentioning before, were unable to detect a 23 dose-response. 24 Q. Do you have your report in</p>	<p>1 Q. You state that it also has been 2 difficult to exactly estimate the quantity of 3 talcum powder administration during personal 4 hygiene activities; is that right? 5 A. That's correct. 6 Q. Let's look at a couple of the 7 studies that you believe do, in fact, show a 8 dose-response. The Penninkilampi, that's a 9 meta-analysis, 2018; is that right? 10 A. That's correct. 11 Q. That study does not consider or 12 include the Gertic 2010 cohort study; is that 13 right? 14 A. I -- I'd have to look at the 15 table, but yes, that one may be left out. 16 Q. Well, that's a significant 17 study to leave out of an analysis, isn't it? 18 MS. O'DELL: Object to the 19 form. 20 THE WITNESS: I'm getting 21 there. 22 (Document review.) 23 THE WITNESS: Apologies, I have 24 binder block here.</p>

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<p>1 MS. O'DELL: You need help?</p> <p>2 THE WITNESS: Okay.</p> <p>3 BY MR. ZELLERS:</p> <p>4 Q. And I misspoke. I meant to</p> <p>5 refer to Gates, the updated Nurses' study.</p> <p>6 So Gates 2010.</p> <p>7 A. Yes, it appears that Gates is</p> <p>8 not included in the -- in the spectrum of</p> <p>9 studies considering; the Gertic study does</p> <p>10 appear.</p> <p>11 Q. Gates 2010 is an important</p> <p>12 cohort study in this area, would you agree?</p> <p>13 MS. O'DELL: Object to the</p> <p>14 form.</p> <p>15 A. It's important, but I think it</p> <p>16 may be considered one of the ones that</p> <p>17 suffered from power issues. It wasn't able</p> <p>18 to determine a relative risk in the</p> <p>19 population that it assessed.</p> <p>20 BY MR. ZELLERS:</p> <p>21 Q. There are a number of the</p> <p>22 case-control studies that did not determine a</p> <p>23 relative risk, at least of statistical</p> <p>24 significance, correct?</p>	<p>1 Q. This is my highlighted copy, so</p> <p>2 I'm sure it wasn't yours.</p> <p>3 A. I'm sorry.</p> <p>4 Q. That's all right. We'll --</p> <p>5 take your time.</p> <p>6 A. Here we are.</p> <p>7 Q. Got it, Exhibit 20?</p> <p>8 A. I think so.</p> <p>9 Q. Do you have the Cramer study in</p> <p>10 front of you?</p> <p>11 A. I do.</p> <p>12 Q. It's a retrospective</p> <p>13 case-control study published in 2016; is that</p> <p>14 right?</p> <p>15 A. That's correct.</p> <p>16 Q. If we look at the table of</p> <p>17 results on page 337, Table 1.</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. This table shows the risk of</p> <p>21 ovarian cancer for women who use talc, talcum</p> <p>22 powder, daily; is that right?</p> <p>23 MS. O'DELL: Object to the</p> <p>24 form.</p>
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<p>1 A. Well, they determined odds</p> <p>2 ratios, which is the equivalent of relative</p> <p>3 risk for a case-control study.</p> <p>4 Q. And in a number of those</p> <p>5 case-control studies, at least 15 out of the</p> <p>6 30 relative risk was not -- or strike that --</p> <p>7 statistical significance was not achieved in</p> <p>8 the study; is that right?</p> <p>9 MS. O'DELL: Object to the</p> <p>10 form.</p> <p>11 A. That's correct.</p> <p>12 BY MR. ZELLERS:</p> <p>13 Q. Let's look at the Cramer paper.</p> <p>14 We've talked about this earlier.</p> <p>15 A. Which one, the 2016?</p> <p>16 Q. Exhibit 20, yes, 2016.</p> <p>17 A. Okay.</p> <p>18 Q. This is another study that you</p> <p>19 cite as being supportive of your</p> <p>20 dose-response opinion; is that right?</p> <p>21 A. Yes.</p> <p>22 Q. Tell me when you have it.</p> <p>23 A. I think you may have picked up</p> <p>24 my copy or the copy that I was looking at.</p>	<p>1 A. It does.</p> <p>2 BY MR. ZELLERS:</p> <p>3 Q. And it's four different periods</p> <p>4 of time; one year, one to five years, five to</p> <p>5 20 years and more than 20 years; is that</p> <p>6 right?</p> <p>7 A. That's correct.</p> <p>8 Q. There was only statistical</p> <p>9 significance found for the time period of one</p> <p>10 to five years of use and more than 20 years</p> <p>11 of use; is that right?</p> <p>12 A. For the first group, the -- for</p> <p>13 those who reported months year of use --</p> <p>14 months per year of use.</p> <p>15 Q. Well, for the first group,</p> <p>16 which was equivalent to one year of daily</p> <p>17 use, there was no statistical significance;</p> <p>18 is that right?</p> <p>19 MS. O'DELL: Object to the</p> <p>20 form.</p> <p>21 A. That -- well, the -- there was</p> <p>22 a positive odds ratio with a nonsignificant</p> <p>23 95% confidence interval.</p> <p>24 ///</p>

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<p style="text-align: right;">Page 262</p> <p>1 BY MR. ZELLERS: 2 Q. Meaning that if you look at 3 this study, that it is certainly possible 4 that because there is not statistical 5 significance, there could be a finding of no 6 risk, correct, no increased risk? 7 A. That's a possibility. 8 Q. Then if we go to the next 9 period, we do show a dose-response for talcum 10 powder use in the year -- years one to five; 11 is that right? 12 A. Well, one to five years of 13 daily use, yes. 14 Q. But then when we look at five 15 to 20 years of daily use, there is not a 16 statistically significant association; is 17 that right? 18 A. That's correct. 19 Q. But then when we go to greater 20 than 20 years, we do find a statistical 21 association; is that right? 22 A. That's correct. 23 Q. If, in fact, there was a true 24 dose-response relationship, you would expect</p>	<p style="text-align: right;">Page 264</p> <p>1 dirty, and it doesn't always work out quite 2 that cleanly. 3 BY MR. ZELLERS: 4 Q. All right. Do you -- well, let 5 me withdraw that. 6 Confounding. You considered 7 and talk about confounding as another one of 8 the Bradford Hill criteria; is that right? 9 MS. O'DELL: Object to the 10 form. 11 A. Confounding, by that you mean 12 specificity? 13 BY MR. ZELLERS: 14 Q. Well, I thought your -- I 15 thought you said in your methodology that you 16 applied the Bradford Hill criteria. 17 A. That's correct. 18 Q. Is confound -- strike that. 19 Is confounding an issue in 20 interpreting epidemiologic studies? 21 A. Yes. 22 Q. Do you agree that there is 23 confounding in these studies? 24 A. I'm sure there's confounding in</p>
<p style="text-align: right;">Page 263</p> <p>1 to see that dose-response relationship in 2 each of these groups; is that right? 3 MS. O'DELL: Object to the 4 form. 5 A. It's more like we see in the 6 group directly below that, where you start 7 out with an odds ratio which is not 8 significant but positive, and then reach a 9 significant odds ratio at one to five years 10 of daily use and a higher amount of 11 significance with five to 20 years of daily 12 use, and still a significant odds ratio, 13 which is about the same level, at greater 14 than 20 years of daily use. 15 BY MR. ZELLERS: 16 Q. Is that a yes to my question, 17 that if you do have a true dose-response 18 relationship, you would expect to see that 19 dose-response continue throughout each of the 20 periods? 21 MS. O'DELL: Object to the 22 form. 23 A. Well, it would be nice if you 24 did that, but epidemiologic data is very</p>	<p style="text-align: right;">Page 265</p> <p>1 these studies. 2 Q. You're familiar with that term, 3 right? 4 A. Yes. 5 Q. That's where the presence of 6 another association confuses the relationship 7 between the exposure and the disease being 8 studied; is that right? 9 A. That's correct. 10 Q. For example, if you're studying 11 the association between coffee and pancreatic 12 cancer, you need to be mindful of whether 13 cigarette smoking is more common in coffee 14 drinkers than the rest of the population, 15 fair? 16 A. Yes. 17 Q. Coffee -- or strike that. 18 Cigarette smoking could be a 19 confounder in that situation? 20 A. Possible. 21 Q. Because if more coffee drinkers 22 are smokers than non-coffee drinkers, an 23 association between coffee drinking and 24 pancreatic cancer might be due to the</p>

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<p style="text-align: right;">Page 266</p> <p>1 smoking, not the coffee drinking; fair?</p> <p>2 A. That would be a good</p> <p>3 description of confounding.</p> <p>4 Q. Confounding can distort results</p> <p>5 in epidemiological studies; is that right?</p> <p>6 A. It can.</p> <p>7 Q. Do you agree that residual</p> <p>8 confounding is possible in every</p> <p>9 observational study?</p> <p>10 A. Yes, I think there's some form</p> <p>11 of confounding that's present in every</p> <p>12 observational study.</p> <p>13 Q. It's possible that unmeasured</p> <p>14 confounders may be present in every</p> <p>15 observational study; is that right?</p> <p>16 A. That's correct. Not just</p> <p>17 unmeasured confounders, but unrecognized</p> <p>18 confounders.</p> <p>19 Q. It's impossible to say that all</p> <p>20 known and unknown confounding factors have</p> <p>21 been controlled for in any given study; is</p> <p>22 that right?</p> <p>23 A. I also agree with that.</p> <p>24 Q. Many new factors possibly</p>	<p style="text-align: right;">Page 268</p> <p>1 not controlled for in any of the talc/ovarian</p> <p>2 cancer studies, were they?</p> <p>3 A. Not that I'm aware of.</p> <p>4 Q. Are you aware that studies that</p> <p>5 show a relationship between talc and ovarian</p> <p>6 cancer did not account for confounders?</p> <p>7 A. I think it's possible that many</p> <p>8 of those studies did not account for all</p> <p>9 potential confounders, but they made attempts</p> <p>10 to.</p> <p>11 Q. For example, Terry 2013, we</p> <p>12 talked about that earlier; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. Terry 2013, that meta-analysis</p> <p>15 did not adjust for hormone replacement</p> <p>16 therapy usage, correct?</p> <p>17 A. Yes.</p> <p>18 Q. If hormone replacement therapy</p> <p>19 is a risk factor for ovarian cancer, then the</p> <p>20 Terry 2013 meta-analysis did not account for</p> <p>21 that potential confounding factor, correct?</p> <p>22 MS. O'DELL: Object to the</p> <p>23 form.</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 267</p> <p>1 involved in ovarian cancer risk are just</p> <p>2 being published in the literature, correct?</p> <p>3 MS. O'DELL: Object to the</p> <p>4 form.</p> <p>5 A. I believe that is true.</p> <p>6 BY MR. ZELLERS:</p> <p>7 Q. For example, history of</p> <p>8 chlamydia infection, have you read about that</p> <p>9 possibly being involved in ovarian cancer</p> <p>10 risk?</p> <p>11 A. I haven't read that</p> <p>12 specifically. I was thinking more about the</p> <p>13 new information regarding genetic</p> <p>14 susceptibilities.</p> <p>15 Q. Also, weight gain during</p> <p>16 adolescence, is that another relatively new</p> <p>17 possible ovarian cancer risk factor?</p> <p>18 MS. O'DELL: Object to the</p> <p>19 form.</p> <p>20 A. It is, but obesity has been</p> <p>21 recognized as a cofactor for many years.</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. History of chlamydia infection,</p> <p>24 weight gain during adolescence, those were</p>	<p style="text-align: right;">Page 269</p> <p>1 BY MR. ZELLERS:</p> <p>2 Q. You cannot say whether the odds</p> <p>3 ratio of the Terry 2013 study would have been</p> <p>4 lower if the authors had adjusted for hormone</p> <p>5 replacement therapy usage, correct?</p> <p>6 A. I cannot say that. Yes.</p> <p>7 Q. Recall bias. You're familiar</p> <p>8 with recall bias?</p> <p>9 A. I am.</p> <p>10 Q. That is also a concern in every</p> <p>11 retrospective study, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Recall bias can distort a</p> <p>14 scientific evaluation of whether an exposure</p> <p>15 is actually related to a disease; is that</p> <p>16 right?</p> <p>17 A. Yes, it can.</p> <p>18 Q. For example, recall bias could</p> <p>19 distort results if women with ovarian cancer</p> <p>20 were more likely to remember their exposure</p> <p>21 to talc than women without ovarian cancer; is</p> <p>22 that right?</p> <p>23 MS. O'DELL: Object to the</p> <p>24 form.</p>

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<p style="text-align: right;">Page 270</p> <p>1 A. That's correct.</p> <p>2 BY MR. ZELLERS:</p> <p>3 Q. The effects of recall bias can</p> <p>4 be very real; is that right?</p> <p>5 MS. O'DELL: Object to the</p> <p>6 form.</p> <p>7 A. I'm not sure what you mean by</p> <p>8 very real.</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. Well, let's look at one of the</p> <p>11 studies that you cite. You cited the</p> <p>12 Schildkraut study in your report and you</p> <p>13 referred to it a bit earlier as supporting</p> <p>14 dose-response; is that right?</p> <p>15 A. Yes.</p> <p>16 Q. That's a study by Schildkraut</p> <p>17 and others titled Association Between Body</p> <p>18 Powder Use and Ovarian Cancer, the</p> <p>19 African-American Cancer Epidemiologic -- or</p> <p>20 Epidemiology Study.</p> <p>21 Is that right?</p> <p>22 A. Yes.</p> <p>23 Q. I've got it here for you.</p> <p>24 A. Okay.</p>	<p style="text-align: right;">Page 272</p> <p>1 publicity from lawsuits might influence the</p> <p>2 participants' recall of prior body powder</p> <p>3 use; is that right?</p> <p>4 A. This was a recent study, so</p> <p>5 that was more likely.</p> <p>6 Q. If you look on page 2,</p> <p>7 right-hand side, last paragraph that starts</p> <p>8 "Covariates include."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And I'm reading about</p> <p>12 two-thirds of the way down: Two class action</p> <p>13 lawsuits were filed in 2014 concerning</p> <p>14 possible carcinogenic effects of body powder</p> <p>15 which may have influenced recall of use;</p> <p>16 therefore, year of interview 2014 or later,</p> <p>17 yes/no, was concluded as a covariate in the</p> <p>18 logistic regression models.</p> <p>19 Is that correct?</p> <p>20 A. That's correct.</p> <p>21 Q. So go to page 4, Table 2. This</p> <p>22 is the adjusted odds ratio for the</p> <p>23 associations between mode, frequency and</p> <p>24 duration of body powder use in ovarian</p>
<p style="text-align: right;">Page 271</p> <p>1 (Carson Deposition Exhibit 24</p> <p>2 marked.)</p> <p>3 BY MR. ZELLERS:</p> <p>4 Q. Deposition Exhibit 24 is the</p> <p>5 Schildkraut study, 2016, correct?</p> <p>6 (Pause.)</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. Did you say correct?</p> <p>9 A. I think I did. I'm sorry.</p> <p>10 Q. That's all right. I may have</p> <p>11 missed it.</p> <p>12 Exhibit 24 is the Schildkraut</p> <p>13 2016 study; is that right?</p> <p>14 A. Yes.</p> <p>15 Q. This is one of the studies that</p> <p>16 you cite to and that you relied on in forming</p> <p>17 your opinions; is that right?</p> <p>18 A. Yes.</p> <p>19 Q. The study looked at, among</p> <p>20 other things, what impact, if any, lawsuit</p> <p>21 filings in 2014 had on whether women recalled</p> <p>22 using talc in the past, correct?</p> <p>23 A. I believe so.</p> <p>24 Q. The authors thought that the</p>	<p style="text-align: right;">Page 273</p> <p>1 cancer; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. The second column shows the</p> <p>4 number of cases, and that would be women with</p> <p>5 ovarian cancer; is that right?</p> <p>6 A. That's correct.</p> <p>7 Q. The third column shows the</p> <p>8 controls; that's the women who do not have</p> <p>9 ovarian cancer, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Looking at this data before</p> <p>12 2014, before the lawsuits, the percentage of</p> <p>13 controls, meaning women without ovarian</p> <p>14 cancer, said they used talc on their genitals</p> <p>15 was 34%; is that right?</p> <p>16 So those are women who were</p> <p>17 interviewed before 2014.</p> <p>18 A. Yes. Any genital use controls,</p> <p>19 34%.</p> <p>20 Q. And the controls, again, are</p> <p>21 women without ovarian cancer.</p> <p>22 A. That's correct.</p> <p>23 Q. The percentage of cases,</p> <p>24 meaning women with ovarian cancer, that were</p>

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<p style="text-align: right;">Page 274</p> <p>1 interviewed before 2014 that said they used 2 talc on their genitals was 36.5%; is that 3 right? 4 A. That's correct. 5 Q. So roughly the same reporting 6 of genital talc use between women with and 7 without ovarian cancer occurred for those 8 women interviewed before the lawsuits were 9 filed; is that right? 10 A. That's correct. 11 Q. Then look at what happened 12 after the lawsuits were filed in 2014. For 13 women interviewed after 2014, the percent of 14 women without ovarian cancer that said they 15 used talc on their genitals was 34.4%; is 16 that right? 17 A. That's correct. 18 Q. So based on this data, the 19 lawsuits had essentially no effect on how 20 many of the women without ovarian cancer, the 21 controls, remembered or recalled using baby 22 powder; is that right? 23 A. Well, the percentage is the 24 same in both cases.</p>	<p style="text-align: right;">Page 276</p> <p>1 BY MR. ZELLERS: 2 Q. In this study, lawsuit filings 3 appears to have affected how many women with 4 ovarian cancer remembered using talc on their 5 genitals but basically had no effect on the 6 memory of women without ovarian cancer; is 7 that right? 8 MS. O'DELL: Object to the 9 form. 10 A. You can't say that this is -- 11 this demonstrates recall bias. It could. 12 BY MR. ZELLERS: 13 Q. These findings could be an 14 example of the potential effect of recall 15 bias; is that right? 16 MS. O'DELL: Object to the 17 form. 18 A. That is correct. 19 BY MR. ZELLERS: 20 Q. So pre-2014 there was an odds 21 ratio of 1.19 with the confidence interval 22 ranging from .87 to -- strike that -- 23 from .87 to 1.63, so there is not statistical 24 significance pre-2014; is that right?</p>
<p style="text-align: right;">Page 275</p> <p>1 Q. It went from 34% to 34.4%; is 2 that right? 3 A. That's correct. 4 Q. For women with ovarian cancer, 5 before the lawsuits were filed, 36.5% of them 6 said they recalled using baby powder; is that 7 right? 8 A. That's right. 9 Q. But after the lawsuits were 10 filed, the percent of women with ovarian 11 cancer who said they used baby powder went up 12 to 51.5%; is that right? 13 A. That is also correct. 14 Q. Is that a significant increase 15 from 36.5%? 16 A. I don't know, but it seems like 17 it might be. 18 Q. So after the lawsuits were 19 filed, the percent of women with ovarian 20 cancer who said they used baby powder jumped 21 significantly; is that right? 22 MS. O'DELL: Object to the 23 form. 24 A. Well, that's -- that is true.</p>	<p style="text-align: right;">Page 277</p> <p>1 A. Probably not. 2 Q. If the study had been 3 terminated as of 2014, prior to the lawsuits 4 being filed, then the results of the study 5 would have been that genital talc use was not 6 statistically significantly associated with 7 an increased risk of ovarian cancer; is that 8 right? 9 MS. O'DELL: Object to the 10 form. 11 A. Yes. 12 BY MR. ZELLERS: 13 Q. Did you make an attempt to 14 account for this potential recall bias in 15 weighing the Schildkraut study? 16 A. The authors did that for me by 17 including the period of the interview as a 18 cofactor in the logistic regression models. 19 It accounts for this difference that you see 20 on the table. 21 Q. You do agree there was no 22 statistically significant finding of an odds 23 ratio prior to 2014, the data collected 24 through that time; is that right?</p>

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<p style="text-align: right;">Page 278</p> <p>1 A. In the -- in the data collected 2 on those -- let me see here. In the data 3 collected on those 351 cases and 4 corresponding controls, there was not a 5 significant odds ratio. 6 Q. I want to go back and ask you a 7 few questions about some of the things I had 8 talked to you before about. 9 In terms of this chatter about 10 IARC, who has told you this? 11 A. There are a number of 12 environmental websites and -- that also 13 operate on social media that discuss this 14 kind of thing. 15 Q. So there's social media 16 websites that have talked about at least the 17 possibility of IARC revisiting the issue? 18 A. Yes, among many other things. 19 Q. I asked you earlier about 20 cornstarch, and you believe that cornstarch 21 is rapidly cleared from the body, including 22 the ovaries; is that right? 23 MS. O'DELL: Object to the 24 form.</p>	<p style="text-align: right;">Page 280</p> <p>1 factors -- or latency periods for a number of 2 different types of cancers and tumors based 3 on the incidence data and what is known about 4 the natural progression of those tumors over 5 time. 6 I can't recall at the moment 7 exactly where I determined the latency period 8 for ovarian cancer to be between 20 and 9 40 years. 10 We do have a paper that's 11 referenced here that discusses the 12 determination of latency periods and includes 13 ovarian cancer as one of the tumors that it 14 determines a latency period for, and it uses 15 a mathematical formula with various factors 16 plugged into it to calculate that. 17 In that particular article, the 18 latency factor -- period was very long. I 19 think it was 44 years on the average. 20 Q. You do not have personal 21 expertise in terms of the latency period for 22 ovarian cancer, correct? 23 A. I have -- I've calculated 24 latency periods as an exercise when I was in</p>
<p style="text-align: right;">Page 279</p> <p>1 A. Yes. 2 BY MR. ZELLERS: 3 Q. What is the mechanism by which 4 you believe that cornstarch is rapidly 5 cleared from the body, including the ovaries? 6 A. It's primarily composed of 7 carbohydrate with a small amount of 8 structural material, probably cellulose, and 9 those materials are broken down in body 10 fluids fairly rapidly and dissolved and 11 become part of the general milieu of the 12 body. 13 Q. Does cornstarch create 14 inflammation in the body? 15 A. Yes. 16 Q. You testified that the latency 17 period for ovarian cancer is between 20 and 18 40 years; is that right? 19 A. Roughly, yes. 20 Q. What is the basis for you 21 saying that? 22 A. There are a number of factors 23 that influence that, but there are 24 organizations that have determined latency</p>	<p style="text-align: right;">Page 281</p> <p>1 graduate school, but that's not something I 2 normally do. I usually defer to the -- those 3 who have published latency periods for that 4 information. 5 Q. You are recalling that at least 6 in some of the study or studies that you've 7 reviewed that the latency period for ovarian 8 cancer is 20 to 40 years, correct? 9 A. Yes. 10 Q. Are you able to tell us which 11 study or studies you're relying on for that 12 information? 13 A. I'd have to go through my list 14 to find it. Do you mind if I take a moment 15 to do that? 16 Q. Define "a moment." 17 A. Well, however long it takes me 18 to find it in that list, but -- 19 Q. Let me see if I can shortcut 20 it. 21 Do you believe that the latency 22 period for ovarian cancer is something you've 23 written out in one of your handwritten notes? 24 A. I don't believe so.</p>

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<p>1 Q. It would be -- where would it 2 be? 3 MS. O'DELL: If you need a 4 moment to review either your report or 5 your materials list, you know -- 6 THE WITNESS: I don't believe 7 that particular piece of information 8 is in my report, but it's -- I think I 9 could come up with it fairly quickly 10 if I -- 11 BY MR. ZELLERS: 12 Q. All right. Go ahead. Find for 13 us the study or studies you're relying on for 14 the latency period of ovarian cancer. 15 A. Okay. If I'm lucky, I may hit 16 on it here. 17 (Document review.) 18 A. It's the Diana Nadler and Igor 19 Zurbenko paper Estimating Cancer Latency 20 Times Using the Weibull Model. 21 BY MR. ZELLERS: 22 Q. You're looking at Exhibit 4, 23 your literature list; is that right? 24 A. Yes.</p>	<p>1 MS. BOCKUS: If you want to 2 pass me your microphone, I think I can 3 stay here. I'm not going to pass him 4 that many exhibits. 5 MR. ZELLERS: I'm happy to help 6 you. 7 MS. BOCKUS: Thank you. 8 EXAMINATION 9 BY MS. BOCKUS: 10 Q. Dr. Carson, my name is Jane 11 Bockus. I'm not certain I actually 12 introduced myself to you this morning, but I 13 represent Imerys in this litigation. 14 Do you understand that? 15 A. I do. 16 Q. Before Mr. Abney contacted you 17 about preparing a report that would explain 18 the relationship between regular perineal use 19 of talc based on personal hygiene products 20 and subsequent development of ovarian cancer, 21 is that anything that you had researched 22 before that date? 23 MS. O'DELL: Object to the 24 form.</p>
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<p>1 Q. What page of Exhibit 4 are you 2 looking at? 3 A. Page 17 in the Ns. 4 Q. Are you finished? 5 A. There may be others in the 6 list, but you asked me to cite one. You want 7 me to continue looking? 8 Q. No, I -- that is sufficient for 9 my purposes. Thank you. 10 Dr. Carson, there have been 11 some studies where talc particles had been 12 observed or reported in the ovaries of women 13 who have had perineal talc use; is that 14 right? 15 A. Yes. 16 Q. Heller was one of the studies 17 that we talked about, correct? 18 A. Correct. 19 Q. In those studies, there has not 20 been inflammation noted; is that right? 21 A. No, there -- that's not been an 22 important finding. 23 MR. ZELLERS: I have no further 24 questions for you.</p>	<p>1 A. I don't think Mr. Abney -- 2 well, he may have been that detailed in our 3 discussion. But in response to your 4 question, that's not a specific question I 5 had researched in the past, although I had 6 researched related kinds of issues. 7 BY MS. BOCKUS: 8 Q. So would it be fair to say that 9 the opinions contained in your report are all 10 opinions that you have come to as a result of 11 doing the research at the request of 12 Mr. Abney and others in the plaintiffs' 13 lawyer group? 14 MS. O'DELL: Object to the 15 form. 16 A. Yes. 17 BY MS. BOCKUS: 18 Q. Okay. And I'm going to 19 apologize right now. I'll be jumping around 20 because most of my outline has already been 21 covered, so let me just get you to look at 22 your report, if I could, and I'm going to ask 23 you some questions about it. 24 Turn to page 4, and</p>

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<p style="text-align: right;">Page 286</p> <p>1 paragraph (b), the first sentence reads: 2 Numerous studies have examined the 3 cancer-causing characteristics of talc. 4 Do you see that? 5 A. Yes. 6 Q. And you identified Wilde as 7 your source for that statement, correct? 8 A. That is correct. 9 Q. Isn't it correct that the Wild 10 study actually exonerated talc as having 11 cancer-causing characteristics? 12 A. That was a conclusion of the 13 author, but the reason it's cited there is 14 because that's an example of the 15 investigation of the relationship. 16 Q. Okay. But in that study, 17 they -- he concluded that talc alone did not 18 cause cancer, correct? 19 A. As I recall, that was the 20 general conclusion, yes. 21 Q. Okay. Then in the next couple 22 of sentences, you say that talc has caused 23 cancer when implanted in various tissues and 24 under the skin in laboratory animals. It</p>	<p style="text-align: right;">Page 288</p> <p>1 A. No. 2 Q. And then going on, you talk 3 about the fact that there in that same 4 paragraph, if you go down, you talk about 5 IARC and the fact that IARC concluded that 6 talcum powder use by women for feminine 7 hygiene is a possible human carcinogen; 8 that's not a classification of talc as a 9 carcinogen, correct? 10 MS. O'DELL: Object to the 11 form. 12 A. It is within the spectrum of 13 carcinogens. 14 BY MS. BOCKUS: 15 Q. It's possible. 16 A. That's correct. 17 Q. And then you say that -- 18 meaning that there is insufficient evidence 19 of carcinogenesis in humans, but strong 20 evidence in other mammalian species. 21 Can you tell me where in IARC 22 it says that there is strong evidence that 23 talc causes ovarian cancer in other mammalian 24 species?</p>
<p style="text-align: right;">Page 287</p> <p>1 causes inflammation and fibrotic reaction, 2 including the chemotaxis of inflammatory 3 immune cells and accelerated growth and 4 division of cells in the involved tissue. 5 And you cite Okada 2007 for 6 that proposition; is that correct? 7 A. That's correct. 8 Q. But Okada wasn't even looking 9 at talc, was it? 10 A. Let me see here. Okada was 11 looking at inflammation as -- as the endpoint 12 in the various components of inflammation 13 which I talked about here, the chemotaxis of 14 inflammatory immune cells, accelerated growth 15 division in the involved tissues. 16 Q. But what you say is that talc 17 causes. When you say "it," you're referring 18 to talc, correct? It causes inflammation and 19 fibrotic reaction; isn't that what you're 20 saying in this sentence? 21 A. It is talc, yes. 22 Q. Okay. And yet, Okada, the 23 study that you cite for that proposition, 24 doesn't look at talc at all, does it?</p>	<p style="text-align: right;">Page 289</p> <p>1 A. I think the issue is not 2 specifically ovarian cancer; the issue is 3 cancer. And that's the point of view of 4 IARC, and that's what's alluded to here. 5 Q. So this is the one exhibit I'm 6 going to hand you, if I can get that one 7 marked by my assistant. 8 MR. ZELLERS: Exhibit 25. 9 (Carson Deposition Exhibit 25 10 marked.) 11 MS. O'DELL: This is a page out 12 of the monograph? 13 MS. BOCKUS: Yes. 14 MS. O'DELL: Are you going to 15 identify it? 16 MS. BOCKUS: And he can look it 17 up in his whole monograph. I just 18 pulled the page for simplicity. 19 MS. O'DELL: So feel free to do 20 that, Doctor. 21 MS. BOCKUS: Yes, page 412. 22 BY MS. BOCKUS: 23 Q. So looking at Exhibit 25, this 24 is a page from the IARC monograph where it</p>

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<p>1 talks about the data -- the evidence that 2 they have and the evidence that they 3 reviewed. 4 Do you see that? 5 A. That's correct. 6 Q. And what they actually state 7 with regard to experimental evidence is that 8 there is limited evidence in experimental 9 animals for the carcinogenicity of talc not 10 containing asbestos or asbestiform fibers. 11 Correct? 12 MS. O'DELL: Object to the 13 form. 14 BY MS. BOCKUS: 15 Q. Did I read it incorrectly? 16 A. No, I just lost you for a 17 moment. 18 Q. It's one sentence. Go ahead 19 and take your time and read it. 20 A. Yes, I agree with that. They 21 found that inhaled talc, which does not 22 contain asbestos or asbestiform fibers, is 23 Group 3. 24 Q. That wasn't my question. I'm</p>	<p>1 black, titanium dioxide and talc. 2 So regarding talc, the overall 3 point of view here is whether or not it 4 produces cancer, not just ovarian cancer, not 5 just lung cancer, but any cancer. 6 And so I'm not sure that that 7 responds to your question. 8 BY MS. BOCKUS: 9 Q. No. My question was: You 10 state in your report that IARC found strong 11 evidence in animals, and I want to know where 12 you believe that statement occurs in the IARC 13 monograph, or do you know? 14 MS. O'DELL: And if you need a 15 minute to look, feel free to do that. 16 A. Well, I can say that it might 17 take me a while to look for it, but I can say 18 that that's the basic definition of Group 2B, 19 is limited evidence in humans and compelling 20 evidence in animals or other -- 21 BY MS. BOCKUS: 22 Q. Tell me where you're looking at 23 that definition of 2B. 24 A. Let me see here.</p>
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<p>1 talking about experimental animals because 2 that's what -- you state in your report that 3 IARC found strong evidence in animals, and 4 yet the part of IARC that I know of where 5 they're addressing the animal data with 6 regard to talc is what I handed you in 7 Section 6.2, and it states there's limited 8 evidence, correct? 9 MS. O'DELL: Objection. 10 A. It states that there's limited 11 evidence -- I need to find this section in 12 the monograph. Just bear with me for a 13 moment. It's page 412? 14 (Document review.) 15 A. Okay. I seem to be missing 16 that part of the monograph. 17 MS. O'DELL: Do you have the 93 18 monograph? 19 THE WITNESS: Where's the -- 20 this is 100C, and this is 93. Okay. 21 Here it is. All right. Okay. 22 A. Okay. The entire monograph is 23 designed to evaluate carcinogenic risk, and 24 it looks at three different species, carbon</p>	<p>1 Q. We earlier marked the... 2 Exhibit 21, I think. 3 A. Well, I have this other 4 exhibit, which is the preamble from another 5 situation; it's Exhibit P-346, and... 6 Q. Well, let me just ask a 7 different question, rather than looking at 8 the preamble. 9 A. All right. 10 Q. Because that's kind of 11 overarching. 12 A. It is. 13 Q. To know what IARC found with 14 regard to talc and the evidence in animal 15 models, wouldn't it be more appropriate to 16 look at what they actually said about talc in 17 the animal studies? 18 A. Yes. 19 MS. O'DELL: Objection, form. 20 A. I would agree that that's the 21 case. 22 BY MS. BOCKUS: 23 Q. And to your knowledge, nowhere 24 did they find strong evidence of</p>

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<p>1 cancer-causing potential of talc in animal 2 studies, correct? 3 MS. O'DELL: Objection to form. 4 A. Well -- well, it says on that 5 page there's limited evidence in experimental 6 animals, so I'll agree that at least in this 7 location it does not say strong evidence. 8 BY MS. BOCKUS: 9 Q. And without going through the 10 entire monograph, you don't know where that 11 language came from, is that fair, that you 12 used in your report? 13 MS. O'DELL: Object. Excuse 14 me. Object to the form. I think he 15 was pointing -- directing you to the 16 preamble and you withdrew your 17 question, but -- 18 MS. BOCKUS: Well, let me just 19 ask a qualifying question. 20 BY MS. BOCKUS: 21 Q. Does the preamble in any way 22 address their findings with regards to talc? 23 A. No, the preamble addresses the 24 methodology that's used by the IARC agency in</p>	<p>1 misstates the evidence. 2 A. I believe that was their 3 assumption. 4 BY MS. BOCKUS: 5 Q. Okay. The studies that you 6 reference in support of the notion that 7 asbestos in -- that may or may not exist in 8 body powder contributes to cause ovarian 9 cancer, none of the studies that you cite to 10 have referenced an application of a product 11 to the perineum of the women and girls study, 12 correct? 13 MS. O'DELL: Object to the 14 form. 15 THE WITNESS: I have a -- I 16 apologize greatly, but I lost the 17 track. Could you repeat that 18 question. 19 MS. BOCKUS: That's totally 20 understandable because it was a little 21 bit convoluted. 22 MS. O'DELL: Do you mind if we 23 get the realtime running again? We're 24 just off track here.</p>
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<p>1 addressing all the substances that they 2 evaluate. 3 Q. Okay. 4 A. And that's usually where I pull 5 things like that. 6 MS. O'DELL: Are you finished, 7 Doctor? 8 THE WITNESS: Unless I'm going 9 to continue to search for this. 10 BY MS. BOCKUS: 11 Q. I don't need for you to look in 12 the preamble, because I'm really only 13 interested in their findings as to talc, not 14 their overarching methodology, that sort of 15 thing. 16 A. Okay. But it's important to 17 point out that this particular monograph is 18 an evaluation of the carcinogenicity of talc 19 that does not contain asbestos or asbestiform 20 fibers, so -- 21 Q. Correct. Which was, from their 22 view, the talc that was included in all of 23 the studies that they reviewed, correct? 24 MS. O'DELL: Objection,</p>	<p>1 MS. BOCKUS: That's okay. 2 BY MS. BOCKUS: 3 Q. I'm looking on page 5. Do you 4 see on page 5 of your report, sir, 5 paragraph (c)? 6 A. Yes. 7 Q. And there you cite one, two, 8 three, four, five, six, seven, eight, nine, 9 10, 11, 12 studies, correct? 10 A. Yes. 11 Q. Do you speak Italian? 12 A. I can read it pretty well. 13 Q. Is that what you did for the 14 Bertolotti study? 15 A. The Bertolotti study. Yes, I 16 read most of it. I may have kibitzed with 17 some of my colleagues about the meaning of a 18 few words. 19 Q. At any rate, all of these 20 studies have to do with heavy occupational 21 exposure to asbestos, correct? 22 MS. O'DELL: Object to the 23 form. 24 A. Yes.</p>

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<p style="text-align: right;">Page 298</p> <p>1 BY MS. BOCKUS: 2 Q. And you don't have any 3 information how the dose of asbestos to which 4 these women were exposed during their heavy 5 occupational exposure compares to any 6 exposure to asbestos from the use of body 7 powder, correct? 8 A. Well, I think these were not 9 all occupational exposures, but I do not have 10 information regarding things like the route 11 of exposure, no. 12 Q. Do you have any information 13 regarding the dose? 14 A. No, I don't. 15 Q. Do you have any information 16 that would compare the dose of asbestos to 17 which the women in these studies were 18 exposed -- 19 A. Well, in some of the studies -- 20 Q. Wait, I haven't finished my 21 question. 22 A. Sorry. 23 Q. -- to any alleged dose of 24 asbestos in body powder?</p>	<p style="text-align: right;">Page 300</p> <p>1 microenvironment, and based on what we know 2 about the mechanism of action of talc as well 3 and even asbestos, they're all similar, and 4 for that reason would be expected to be 5 additive. 6 Q. But the study hasn't been done 7 even in a petri dish, has it? 8 MS. O'DELL: Object to the 9 form. 10 A. I don't know if there's 11 something in progress or not, but that's the 12 kind of study that is currently being looked 13 at. Combined exposures is the -- sort of the 14 hallmark of research these days in 15 toxicology. 16 BY MS. BOCKUS: 17 Q. Do you know of anyone who's 18 looking at that question? 19 A. I don't. 20 Q. Okay. Have any of the heavy 21 metals that you have identified been 22 identified as carcinogenic to the ovary by 23 IARC? 24 A. No.</p>
<p style="text-align: right;">Page 299</p> <p>1 Can you make any comparison 2 whatsoever to the amount of asbestos to which 3 these women were exposed to any exposure by 4 any woman who has used a Johnson & Johnson 5 body powder? 6 MS. O'DELL: Object to the 7 form. 8 A. I don't think I'm able to make 9 that kind of comparison. 10 BY MS. BOCKUS: 11 Q. Okay. There are ways to study 12 whether two toxins combined increase a risk 13 more than exposure to a single toxin, whether 14 it -- whether one offsets the risk of one of 15 the toxins or whether you add them together, 16 even multiply them together, right? 17 A. Yes. 18 Q. Has any such study ever been 19 done with regard to talc and the heavy metals 20 that you identify in your report? 21 A. Not specifically a study to 22 look at the combined contribution, but we 23 know a lot about the mechanism of action of 24 the metals in particular in the</p>	<p style="text-align: right;">Page 301</p> <p>1 Q. I want you to turn to page 7 2 now, if you would, please, on other evidence. 3 And you've talked about this paragraph a fair 4 amount already, and I don't want to repeat 5 any of the prior questions. 6 But I want to ask you about the 7 statement in that first sentence, where you 8 say that transport of talc-containing 9 materials from the perineum to the upper 10 reproductive tract and body cavities has been 11 shown to occur with startling regularity. 12 And I want to stop right there. 13 If I recall your testimony 14 correctly, none of these studies even look at 15 the transport of talc-containing materials 16 from the perineum to the upper reproductive 17 tract; isn't that correct? 18 MS. O'DELL: Object to the 19 form. 20 A. Well, it is true that most of 21 the research that's been done in this area 22 has been done on materials that have been 23 instilled into the vagina or the posterior 24 fornix, but I think and it's my opinion that</p>

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<p>1 application to the perineum is equivalent to</p> <p>2 that.</p> <p>3 Q. Do you have an opinion as to</p> <p>4 what percentage of the talcum powder applied</p> <p>5 in a daily dusting to the perineum makes its</p> <p>6 way to the vagina?</p> <p>7 A. No, I don't know.</p> <p>8 Q. Do you have an opinion as to</p> <p>9 what percentage of the talc that, in your</p> <p>10 opinion, would make its way to the vagina</p> <p>11 would actually make its way to the cervix?</p> <p>12 A. I don't know that either.</p> <p>13 Q. And out of the talc that makes</p> <p>14 its way to the cervix, what percentage makes</p> <p>15 it past the cervix into the uterus?</p> <p>16 A. That, I don't know either.</p> <p>17 Q. Do you have any reason to</p> <p>18 believe that talc would migrate with more</p> <p>19 frequency or rapidity than sperm?</p> <p>20 MS. O'DELL: Objection to form.</p> <p>21 A. No, I don't have reason to</p> <p>22 believe that would be the case.</p> <p>23 BY MS. BOCKUS:</p> <p>24 Q. Would you agree, in fact, that</p>	<p>1 those studies that you list here done in</p> <p>2 women who were standing up?</p> <p>3 A. The studies that I list in</p> <p>4 other evidence?</p> <p>5 Q. Yes.</p> <p>6 A. I think not.</p> <p>7 Q. In fact, were any of them done</p> <p>8 in women who were inclined with their head</p> <p>9 elevated over their hips?</p> <p>10 A. No.</p> <p>11 Q. So my question is: Where do</p> <p>12 you get the term "startling regularity" with</p> <p>13 regard to the transport of talc from outside</p> <p>14 a woman's body to the upper reproductive</p> <p>15 tract?</p> <p>16 MS. O'DELL: Object to the</p> <p>17 form.</p> <p>18 A. The propensity of evidence of</p> <p>19 rapid transport of particulate material</p> <p>20 regarding -- regardless of its composition.</p> <p>21 BY MS. BOCKUS:</p> <p>22 Q. Particulate material inserted</p> <p>23 well into a woman's vagina whose hips are</p> <p>24 above her head, correct?</p>
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<p>1 it is unlikely that talc, an inert particle,</p> <p>2 would travel as quickly or in the same</p> <p>3 percentages as sperm through the reproductive</p> <p>4 tract?</p> <p>5 MS. O'DELL: Object to the</p> <p>6 form.</p> <p>7 A. I think the transport time is</p> <p>8 roughly the same for any particulate matter,</p> <p>9 including sperm.</p> <p>10 BY MS. BOCKUS:</p> <p>11 Q. Do you have any studies to</p> <p>12 support that opinion?</p> <p>13 A. Well, we know -- we know the --</p> <p>14 we know the velocity of motile sperm; it's</p> <p>15 very slow. And we have studies that have</p> <p>16 shown the progression of particles through</p> <p>17 the fallopian tubes at at least that fast a</p> <p>18 rate, possibly faster.</p> <p>19 And so the motility of sperm is</p> <p>20 slower than the rate at which it passes</p> <p>21 through the female reproductive system, so</p> <p>22 there are obviously other mechanisms at play</p> <p>23 other than sperm motility.</p> <p>24 Q. To your knowledge, were any of</p>	<p>1 MS. O'DELL: Objection to form.</p> <p>2 A. Well, we have other studies</p> <p>3 too. We have the powdered glove examination</p> <p>4 studies, things of that nature, that are a</p> <p>5 little bit different.</p> <p>6 BY MS. BOCKUS:</p> <p>7 Q. And you believe they support</p> <p>8 your conclusion that talc is transported from</p> <p>9 the perineum to the upper reproductive tract</p> <p>10 with startling regularity?</p> <p>11 A. I think that's a valid</p> <p>12 conclusion supported by the evidence, yes.</p> <p>13 Q. I'm turning to page 8 now, and</p> <p>14 the number that you have here -- and you've</p> <p>15 repeated it a couple of times today -- about</p> <p>16 your opinion that the elimination of talc as</p> <p>17 a risk could result in over 3,000 lives saved</p> <p>18 in the U.S. each year.</p> <p>19 How did you come to that</p> <p>20 conclusion?</p> <p>21 A. Well, I'm referring to talcum</p> <p>22 powder here --</p> <p>23 Q. Okay. Sure.</p> <p>24 A. -- which is the complete</p>

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<p>1 product.</p> <p>2 I came to that conclusion based</p> <p>3 on the number of new cases of ovarian cancer</p> <p>4 that are diagnosed in the United States each</p> <p>5 year and the number of ovarian cancer deaths</p> <p>6 that occur each year.</p> <p>7 And essentially, of 21,000 or</p> <p>8 so cases of -- new cases of ovarian cancer,</p> <p>9 there are corresponding 14,000 or more deaths</p> <p>10 each year, so that's a two-thirds fatality</p> <p>11 rate if you look over time.</p> <p>12 The -- at 30% increase in the</p> <p>13 risk of -- or a 30% increase in the risk of</p> <p>14 cancer applied in reverse, that is reducing</p> <p>15 those -- that 30% increased risk from the use</p> <p>16 of perineal application of talcum powder</p> <p>17 could result in the prevention of as many as</p> <p>18 3,000 lives, depending on the prevalence of</p> <p>19 use.</p> <p>20 Q. Would that calculation require</p> <p>21 that 100% of the women in the U.S. be using</p> <p>22 talcum powder on a daily basis?</p> <p>23 A. It would require a hundred</p> <p>24 percent of the women in the U.S. to stop</p>	<p>1 A. There may not have been use of</p> <p>2 talcum powder in all those women, that's</p> <p>3 correct.</p> <p>4 Q. Do you have any notion as to</p> <p>5 what percent of those women may have used</p> <p>6 talcum powder?</p> <p>7 A. Based on these various studies,</p> <p>8 it seems to vary between 30 and 60%. It's</p> <p>9 more so in the U.S., Australia and the U.K.</p> <p>10 Q. Do you have an opinion as to</p> <p>11 how regularly a women needs to use talcum</p> <p>12 powder before her risk of ovarian cancer is</p> <p>13 increased by 30%?</p> <p>14 A. Well, based on the epidemiology</p> <p>15 studies, that risk occurs in the population</p> <p>16 in general from ever use as opposed to never</p> <p>17 use, and so it would depend on the individual</p> <p>18 woman.</p> <p>19 Each person has an individual</p> <p>20 susceptibility and individual characteristics</p> <p>21 and would probably have an individual use</p> <p>22 pattern. So I couldn't say for any</p> <p>23 individual woman.</p> <p>24 Q. And that's not what I'm asking</p>
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<p>1 using talcum powder on a daily basis.</p> <p>2 Q. That wasn't my question.</p> <p>3 In order to attribute --</p> <p>4 A. Well, my answer to your</p> <p>5 question then is no.</p> <p>6 Q. In order to attribute 30% of</p> <p>7 all ovarian cancer deaths to the use of</p> <p>8 talcum powder -- let me back up.</p> <p>9 The data that you have that</p> <p>10 you've cited is talking about the percentage</p> <p>11 of women -- the percentage of women who use</p> <p>12 talcum powder who are diagnosed with ovarian</p> <p>13 cancer, correct?</p> <p>14 MS. O'DELL: Object to the</p> <p>15 form.</p> <p>16 A. It is the total number of new</p> <p>17 diagnoses per year.</p> <p>18 BY MS. BOCKUS:</p> <p>19 Q. Okay.</p> <p>20 A. I think last year was</p> <p>21 22,000-something.</p> <p>22 Q. But that number, 22,000, 100%</p> <p>23 of those women did not use talcum powder,</p> <p>24 correct?</p>	<p>1 for. I'm really asking for in general,</p> <p>2 because that's what epidemiology is, correct?</p> <p>3 It's not talking about an individual woman,</p> <p>4 right?</p> <p>5 A. That's correct, it's describing</p> <p>6 it in the population.</p> <p>7 Q. So in the population, in the</p> <p>8 studies that you've reviewed, what is the</p> <p>9 minimum number of days per month, or however</p> <p>10 you want to describe it, that a woman would</p> <p>11 need to use talcum powder before she would be</p> <p>12 included in the group that you believe have a</p> <p>13 30% increased risk of ovarian cancer?</p> <p>14 MS. O'DELL: Object to the</p> <p>15 form.</p> <p>16 A. The only qualifier that I've</p> <p>17 been able to come up with and that I've used</p> <p>18 in this report is the regular use of talcum</p> <p>19 powder.</p> <p>20 BY MS. BOCKUS:</p> <p>21 Q. Okay.</p> <p>22 A. And that is going to vary over</p> <p>23 a broad range. It would be periodically</p> <p>24 daily to several times a week would be</p>

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<p style="text-align: right;">Page 310</p> <p>1 regular use. 2 Q. And over how many years must a 3 woman use talcum powder on a regular basis 4 before her risk of ovarian cancer is 5 increased to 30% -- 6 MS. O'DELL: Object to the 7 form. 8 BY MS. BOCKUS: 9 Q. -- in your opinion? 10 MS. BOCKUS: Sorry. 11 A. Some of the studies have 12 focused on usage periods as short as one 13 year, but most have studied longer periods of 14 use and separated use into things like 15 decades or accumulated total person-years 16 based on reports of the women, multiplying 17 frequency by time. 18 So again, it would depend on 19 the individual, but the research reports 20 hover around five to ten years of regular 21 use, resulting in significant odds ratios. 22 BY MS. BOCKUS: 23 Q. As I understand it in 24 toxicology, one of the basic tenets is that</p>	<p style="text-align: right;">Page 312</p> <p>1 no threshold of exposure for risk; that we 2 are -- we are right to use a zero threshold 3 approach until we know more about the 4 possibility of a threshold below which 5 exposure would be safe. At the current time 6 we don't have that information. 7 Q. Do you believe that there 8 probably is a threshold below which use is 9 safe? 10 A. In the carcinogenic process, 11 which we haven't really talked about in this 12 session today, there is an insult to a cell 13 which affects the genetic material, the DNA. 14 And there are built-in repair mechanisms that 15 the cell has for fixing that problem that 16 occurred, a mutation, for example. 17 These kinds of insults are 18 happening to cells all the time, not just 19 from carcinogens in our environment, but just 20 from natural occurrences, even endogenous 21 biochemical reactions cause these problems. 22 The question is: Is the repair 23 process sufficient to undo what's been done? 24 And an exposure to environmental carcinogens,</p>
<p style="text-align: right;">Page 311</p> <p>1 it's the dose that makes the poison, correct? 2 A. That's correct. 3 Q. That water can kill you if you 4 drink too much of it, right? 5 A. Theoretically. 6 Q. In a short period of time. 7 And so I'm trying to find out 8 what you have determined is the threshold of 9 risk is -- for talcum powder use by women. 10 Do you have an opinion as to at what point a 11 threshold has been reached where the use of 12 talcum powder by women in their perineal 13 region increases their risk? 14 A. I think any use of carcinogenic 15 materials or any exposure to carcinogenic 16 materials increases the risk somewhat. A 17 greater exposure, based on the 18 "dose makes the poison" principle, would 19 result in a greater risk. 20 And we know from toxicologic 21 studies that intense exposures can sometimes 22 accelerate the process and even shorten the 23 latency period of a carcinogenic event. 24 So my opinion is that there is</p>	<p style="text-align: right;">Page 313</p> <p>1 that repair process is often overwhelmed so 2 that it cannot catch up with the damage 3 that's being created, and a tumor is born, 4 basically. 5 That is where the concept of 6 threshold comes from. Have we overwhelmed 7 the repair or not, and we don't have enough 8 research evidence or scientific evidence to 9 be able to define that line at this point. 10 Q. Has there ever been a study 11 that showed that talcum powder caused DNA 12 damage in normal ovarian epithelial tissue? 13 A. Well, we do have the studies 14 that have recently been produced by Fletcher 15 and Saed that show the inflammatory process 16 is influenced by talc, and this is nonfibrous 17 talc, that result in mutagenic events that 18 are available for promotion, and there are 19 biomarkers that have also been established 20 for that. 21 Q. The studies by Saed did not 22 demonstrate DNA mutation, did they? 23 MS. O'DELL: Object to the 24 form.</p>

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<p style="text-align: right;">Page 314</p> <p>1 A. I think they actually did. 2 BY MS. BOCKUS: 3 Q. That's your reading of them? 4 A. Yes. 5 Q. What Saed did is he placed talc 6 on cultured ovarian cancer cells, correct? 7 A. Yes. 8 Q. And that actually -- what he 9 recorded was an elevation in the CA-125? 10 A. That's one of the things he 11 did. He also measured -- he did a number of 12 genetic studies. He did transcribed RNA. He 13 located individual SNPs, which are single 14 nucleotide polymorphisms, in the genetic 15 material. 16 And he found that as a result 17 of that treatment, those mutations altered 18 the effectiveness of antioxidant enzymes that 19 are part of the protection mechanism and 20 shield the repair process of the cell from 21 further damage. 22 Q. Let's go back to the CA-125. 23 MS. O'DELL: If you need to 24 pull the paper out, Doctor, just, if</p>	<p style="text-align: right;">Page 316</p> <p>1 THE WITNESS: I'm sorry, it 2 appears that I do need to get the 3 original paper here. There it is. 4 Okay. Thank you. 5 (Document review.) 6 BY MS. BOCKUS: 7 Q. Can you answer the question: 8 Did Saed have any either positive or negative 9 controls that he used in his experiments? 10 MS. O'DELL: Object to the 11 form. 12 A. I think he did, but I'd like to 13 actually find it in here so I can give you 14 the specifics. 15 Well, he used normal cells and 16 epithelial ovarian cancer cells, and one was 17 the control for the other. He treated them 18 in the same way. 19 BY MS. BOCKUS: 20 Q. Let me ask a different 21 question. 22 What I'm asking is: Did he 23 use, say, glass beads to see if -- as a 24 control to the talc? Did he have anything</p>
<p style="text-align: right;">Page 315</p> <p>1 you want to take a moment and do that. 2 I know you were searching for it while 3 you were talking. 4 THE WITNESS: Yes, I think I 5 have it right here. 6 MS. BOCKUS: These are just 7 general questions that I'm going to 8 ask you. 9 MS. O'DELL: You still may get 10 the paper out. 11 MS. BOCKUS: Do whatever you 12 want to do. 13 THE WITNESS: You can go ahead. 14 I'm... 15 BY MS. BOCKUS: 16 Q. What controls did Saed use? 17 Did he use any controls? In other words, did 18 he place a known foreign object that was 19 not -- that was known not to be a carcinogen 20 on the cultured ovarian cells to see if there 21 was a difference? 22 MS. O'DELL: Can you just pause 23 just for a minute, let the doctor pull 24 out the exhibit?</p>	<p style="text-align: right;">Page 317</p> <p>1 that he was controlling the cells' reaction 2 to against the talc? 3 A. I don't believe so. 4 Q. That would be important in an 5 experiment of this nature, would you not 6 agree with that? 7 MS. O'DELL: Object to the 8 form. 9 A. Well, he did utilize normal and 10 cancerous cells, which would theoretically 11 act as a control in that experiment. 12 BY MS. BOCKUS: 13 Q. That's not my question. I'm 14 really asking about another element that he 15 is exposing the cells to, both the normal and 16 the cancerous cells. 17 MS. O'DELL: Objection to form. 18 BY MS. BOCKUS: 19 Q. To see if the reaction was just 20 a reaction to a foreign body versus talc 21 specifically. 22 Did he do that? 23 MS. O'DELL: Object to the 24 form.</p>

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<p style="text-align: right;">Page 318</p> <p>1 A. I don't believe that he 2 provided a control exposure as part of this 3 experiment. 4 BY MS. BOCKUS: 5 Q. And you would agree that there 6 are many things that will increase a CA-125, 7 correct? 8 MS. O'DELL: Object to the 9 form. 10 A. Yes, it's an acute-phase 11 reactant. 12 BY MS. BOCKUS: 13 Q. Pregnancy can increase 14 somebody's CA-125? 15 A. That's correct. 16 Q. And with regard to the SNPs, 17 that is not the same thing as a test showing 18 mutation, correct? 19 MS. O'DELL: Object to the 20 form. 21 BY MS. BOCKUS: 22 Q. It's a surrogate. 23 A. Well, it's because there was 24 transcribed RNA that was used to determine</p>	<p style="text-align: right;">Page 320</p> <p>1 A. I don't specifically know. 2 BY MS. BOCKUS: 3 Q. There's no way to know that, is 4 there? 5 A. No, there's not. 6 Q. Let me find my -- there we go. 7 The Saed paper that you were 8 looking at just a minute ago, it has 9 something printed across it. What does that 10 say? 11 A. In blue here? 12 Q. Uh-huh. 13 A. "For Peer Review." 14 Q. Okay. So it hasn't yet been 15 peer reviewed; is that correct? 16 MS. O'DELL: Object to the 17 form. 18 A. It's been submitted. 19 BY MS. BOCKUS: 20 Q. So does that mean it has not 21 yet been peer reviewed? 22 MS. O'DELL: Object to the 23 form. 24 A. I think it's been accepted for</p>
<p style="text-align: right;">Page 319</p> <p>1 their presence, and the -- it's just part of 2 their procedure, but it identifies genetic 3 alterations. And those genetic alterations 4 transformed into differential enzyme 5 activities. 6 Q. Do you know whether there are 7 standard tests for genotoxicity and 8 mutagenicity? 9 A. There are lots of standard 10 tests, yes. 11 Q. And Saed didn't use any of 12 those, did he? 13 MS. O'DELL: Object to the 14 form. 15 A. Well, he went directly to cells 16 in culture to see what happened when they 17 were treated with talc. 18 BY MS. BOCKUS: 19 Q. Does the amount of talc that 20 Saed used compare in any way to the amount of 21 talc that may reach a woman's ovary from 22 perineal application? 23 MS. O'DELL: Object to the 24 form.</p>	<p style="text-align: right;">Page 321</p> <p>1 publication. 2 BY MS. BOCKUS: 3 Q. But the copy you have says on 4 it "For Peer Review," correct? 5 A. That's correct. 6 Q. In the paragraph that we were 7 looking at earlier, where you were talking 8 about the startling regularity, later on in 9 the paragraph you state that there 10 is clearly -- sufficient particulate 11 materials applied routinely to the perineum 12 have ready access and in sufficient 13 quantities to produce biologic responses in 14 internal tissues. 15 What internal tissues have you 16 seen any study recording a biologic response 17 to talc from? 18 That was such a bad question, 19 I'm going to ask it again. 20 What internal tissues are you 21 referring to there? 22 A. Well, it says including -- 23 including ovaries and surrounding structures. 24 By surrounding structures, I'm referring to</p>

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<p style="text-align: right;">Page 322</p> <p>1 the fallopian fimbriae and the epithelium of 2 the cavity. 3 Q. So -- and I know we've been 4 through this already, but to your knowledge, 5 there are no studies reporting biologic 6 responses to talc in the vagina, correct? 7 A. Not that I'm aware. 8 Q. You're not aware of any studies 9 reporting biologic responses to talc in the 10 cervix, correct? 11 A. Correct. 12 Q. Are you aware of any studies 13 reporting biologic response to the uterus? 14 A. No. 15 Q. Are you aware of any studies 16 reporting a biologic response in the 17 fallopian tubes? 18 MS. O'DELL: Object to the 19 form. 20 A. Well, I don't -- I'm not aware 21 of studies that draws a direct correlation 22 between exposure to talc and reaction in the 23 fallopian tubes. 24 ///</p>	<p style="text-align: right;">Page 324</p> <p>1 fallopian tube goes into that fluid and just 2 gets moved around all the time; is that 3 correct? 4 MS. O'DELL: Objection. Excuse 5 me. Objection, form. 6 A. Well, there's a fairly direct 7 presentation of the ovary, so there's not a 8 large space there, but there is a space. And 9 whatever goes into that space remains there. 10 Some of it may come back out. 11 BY MS. BOCKUS: 12 Q. Does the fallopian tube move 13 around during the month? 14 MS. O'DELL: Object to the 15 form. 16 A. I don't know. 17 MS. BOCKUS: I'm almost 18 finished. I'm going through all the 19 things that I've crossed off. 20 BY MS. BOCKUS: 21 Q. So I understand you correctly, 22 you have not identified a nonthreshold dose 23 of talc; is that correct? 24 MS. O'DELL: Object to the</p>
<p style="text-align: right;">Page 323</p> <p>1 BY MS. BOCKUS: 2 Q. Okay. Is the ovary attached to 3 the fallopian tube? 4 A. It is -- it's in the proximity. 5 It's not directly attached. 6 Q. And what surrounds the ovary? 7 A. There's a structure that -- the 8 ovary itself? 9 Q. Yes. 10 A. There's an epithelial membrane 11 around the ovary, and -- 12 Q. And then what touches the 13 epithelial membrane? 14 A. Well, the fimbriae of the 15 fallopian tubes surround that and the rest of 16 it is just sort of space. 17 Q. Space. Is the space filled 18 with fluid? 19 A. It is. 20 Q. And is that fluid kind of 21 moving around? 22 A. All the time. 23 Q. All the time. 24 So things that come through the</p>	<p style="text-align: right;">Page 325</p> <p>1 form. 2 A. You mean a dose that is below a 3 safe threshold? 4 BY MS. BOCKUS: 5 Q. Correct. 6 A. No, I have not. 7 Q. Did you make any attempt to 8 extrapolate a de minimis risk level? 9 MS. O'DELL: Object to the 10 form. 11 A. I did not. It would be nice to 12 be able to do that, considering that most of 13 us have had talcum powder exposures of one 14 sort or another during our lives. And it's 15 something that seems to have been felt to be 16 very useful. 17 So it would be nice to be able 18 to do that exercise, but I haven't -- I have 19 not been prevented -- presented with the 20 information to approach that, nor am I aware 21 of anyone else who's been able to do it. 22 BY MS. BOCKUS: 23 Q. What information would you need 24 that you don't have?</p>

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<p>1 A. Well, we'd need -- we'd need 2 dose information, first of all, which we 3 don't have, to combine with the epidemiologic 4 results. 5 We need to define the 6 mechanistic issues better than they are 7 currently, and at that point I think we would 8 be able to make some strong conclusions 9 regarding potential thresholds of hazardous 10 doses. 11 Q. You would agree that the great 12 majority of women who use talcum powder on a 13 regular basis are never diagnosed with 14 ovarian cancer, correct? 15 A. I think that's true. 16 Q. And it's also true that the 17 majority of women diagnosed with ovarian 18 cancer have never used talcum powder on a 19 regular basis, correct? 20 MS. O'DELL: Object to the 21 form. 22 A. I think it's a majority, but 23 there's a significant number who have. 24 ///</p>	<p>1 you? In other words, are they referred by 2 other people? 3 A. I have primarily a referral 4 practice in toxicology. 5 Q. In toxicology? And so what 6 types of patients are referred to you? 7 A. I have patients who are either 8 workplace-related patients who have had 9 chemical or other substance exposures. I 10 also have a number of environmental exposure 11 patients that I see. 12 And I also have a number of -- 13 I also see a number of patients for general 14 routine surveillance activities or required 15 exams by regulation, either for licensure or 16 certification. 17 Q. Are you sent patients where the 18 patient is trying to figure out why they got 19 some disease? 20 A. Sometimes. Usually the patient 21 comes and tells me why they got the disease, 22 and I go -- I talk to them about the 23 possibilities, and we look at ways of 24 confirming that or refuting it, or in many</p>
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<p>1 BY MS. BOCKUS: 2 Q. But the majority have not, 3 correct? 4 A. I would say more than 50% have 5 not. 6 Q. And would you agree that -- let 7 me back up. 8 When is the last time you 9 conducted a pelvic exam? 10 A. I haven't done one in a couple 11 of years. 12 Q. Under what circumstances did 13 you do it two years ago? 14 A. I see patients regularly, and 15 in some cases, pelvic exams are either 16 requested or indicated by the issue. 17 Q. It's not something you do on a 18 regular basis, correct? 19 A. It's not. 20 Q. And you do not -- what 21 percentage of your patients are women? 22 A. Probably half, maybe a little 23 less than half. 24 Q. How do patients come to see</p>	<p>1 cases, altering to a correct path of 2 diagnostic investigation. 3 Q. So sometimes a patient comes to 4 you and says: I was exposed to this chemical 5 and that's why I can't breathe? 6 A. Yes. 7 Q. And you do an investigation, 8 and sometimes you say: You know what, that 9 chemical has nothing to do with why you can't 10 breathe? 11 A. Sometimes that's the case. 12 MS. O'DELL: Are you finished, 13 sir? Are you finished? 14 A. Well, I just wanted to add -- 15 BY MS. BOCKUS: 16 Q. Sure. 17 A. -- that although many times it 18 is the case, and often the patient does 19 understand that connection quite well, 20 usually from a very closely connected cause 21 and effect kind of relationship. It's when 22 things are stretched out much more in time, 23 and there is a likely suspect that may be an 24 innocent bystander, that they may get</p>

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<p style="text-align: right;">Page 330</p> <p>1 confused.</p> <p>2 Q. Have you ever been referred a</p> <p>3 patient to determine why they have ovarian</p> <p>4 cancer?</p> <p>5 A. No.</p> <p>6 Q. Do you know of any methodology</p> <p>7 accepted in the medical community for</p> <p>8 determining why an individual woman has</p> <p>9 developed ovarian cancer?</p> <p>10 MS. O'DELL: Object to the</p> <p>11 form.</p> <p>12 A. Other than genetic testing that</p> <p>13 identifies specific risks and history taking</p> <p>14 that might identify other known risk factors</p> <p>15 for that woman, there is -- I don't believe</p> <p>16 that there is any good or prescribed</p> <p>17 procedure for making that determination, and</p> <p>18 there is no reasonable screening test that</p> <p>19 can find that cancer when it is at an early</p> <p>20 stage.</p> <p>21 BY MS. BOCKUS:</p> <p>22 Q. Do you believe that obesity</p> <p>23 causes ovarian cancer?</p> <p>24 A. It certainly seems to be</p>	<p style="text-align: right;">Page 332</p> <p>1 for that population of women?</p> <p>2 A. Well, it varies depending on</p> <p>3 the research study that has been done, but</p> <p>4 I've seen odds ratios or relative risks all</p> <p>5 the way from 1 or even below to very high</p> <p>6 numbers, like 20 to 50.</p> <p>7 Q. 20.0, is that what you're</p> <p>8 saying?</p> <p>9 A. Yes, 20.0.</p> <p>10 Q. Not 1.2, but 20.0?</p> <p>11 A. Correct.</p> <p>12 Q. Okay.</p> <p>13 A. Which is a -- which would be 20</p> <p>14 times the normal risk without the exposure.</p> <p>15 Q. Okay. So we've got obesity and</p> <p>16 heavy exposure to asbestos. Any other risk</p> <p>17 factors that you're familiar with?</p> <p>18 MS. O'DELL: Objection --</p> <p>19 excuse me. Objection, misstates the</p> <p>20 doctor's testimony.</p> <p>21 You may answer.</p> <p>22 THE WITNESS: Okay.</p> <p>23 A. Other risk factors for ovarian</p> <p>24 cancer would include things like early</p>
<p style="text-align: right;">Page 331</p> <p>1 related to the occurrence of ovarian cancer</p> <p>2 from a statistical point of view.</p> <p>3 Q. What is the increase in a</p> <p>4 woman's risk of ovarian cancer if she's obese</p> <p>5 compared to a nonobese woman?</p> <p>6 A. In terms of numbers?</p> <p>7 Q. Yes, sir.</p> <p>8 A. I don't know the -- I don't</p> <p>9 know the numbers.</p> <p>10 Q. What other risk factors are you</p> <p>11 familiar with for ovarian cancer?</p> <p>12 A. Well, certainly work with</p> <p>13 asbestos is a risk factor, and we have a</p> <p>14 number of studies that have shown women</p> <p>15 working in the asbestos industry or women who</p> <p>16 are married to asbestos workers and have</p> <p>17 secondary exposure presumably from that are</p> <p>18 at risk for ovarian cancer.</p> <p>19 There are --</p> <p>20 Q. Let me stop you just one</p> <p>21 second.</p> <p>22 A. Yes.</p> <p>23 Q. What percentage -- what is</p> <p>24 their relative risk or what is the odds ratio</p>	<p style="text-align: right;">Page 333</p> <p>1 menarche, late menopause, never being</p> <p>2 pregnant. These are some of the more common</p> <p>3 risk factors that are identified.</p> <p>4 There are genetic risk factors</p> <p>5 that are known, like the BRCA mutations,</p> <p>6 which confer an increased risk. Family</p> <p>7 history.</p> <p>8 BY MS. BOCKUS:</p> <p>9 Q. Do you know the odds ratios of</p> <p>10 any of the risk factors that you just</p> <p>11 identified of never having children, having</p> <p>12 early menarche or late menopause?</p> <p>13 A. Right offhand, I don't know</p> <p>14 what those odds ratios -- the range of those</p> <p>15 are.</p> <p>16 Q. Do you know if any of those</p> <p>17 odds ratios exceed 1.3?</p> <p>18 A. I think they do.</p> <p>19 Q. Does that lead you to conclude</p> <p>20 that those things cause ovarian cancer?</p> <p>21 A. It certainly argues for that.</p> <p>22 The -- there's a risk factor that derives</p> <p>23 from something. You need a mechanism to fill</p> <p>24 in the blank.</p>

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<p style="text-align: right;">Page 334</p> <p>1 But also, some of these risk 2 factors are so common in the population that 3 we can concoct large cohort studies that will 4 have -- can have very low relative risks, 5 like on the order of 1.3 or even lower, and 6 still a significant result. 7 So the more common a factor is, 8 the easier it is to do the research and the 9 more likely you'll get a finding that's 10 relevant to interpretation. 11 Q. What pushes a talc particle 12 from the perineum into the vagina? 13 A. Probably mostly the law of mass 14 action. It simply goes of its own volition. 15 These small particles are always in motion 16 through molecular forces, and they simply 17 move in all directions, and some of them move 18 in that direction. 19 Q. Would that be true for any 20 small particles applied to a woman's 21 perineum? 22 A. Yes. 23 Q. Are you board certified in 24 medical toxicology?</p>	<p style="text-align: right;">Page 336</p> <p>1 Q. So you think you just ran into 2 her? 3 A. Yeah. 4 Q. The other people that you 5 identified that you discussed your report 6 with, did you ask them to read your report? 7 A. I asked them to look at parts 8 of it, early drafts of it to let me know if 9 they thought I was making sense. 10 Q. And did they offer you comments 11 and suggestions for changes in your paper? 12 A. Not really. Mostly they gave 13 me a pat on the back and said: I think 14 you're doing a good job, just sort of beef 15 this part up, and what do you mean by this, 16 maybe I could rephrase that. That sort of 17 thing. 18 Q. Did they give you written 19 suggestions? 20 A. No, these were all verbal 21 comments. 22 Q. Had you given them a hard copy 23 of the portions of your report that you 24 wanted them to comment on?</p>
<p style="text-align: right;">Page 335</p> <p>1 A. I'm not. I started practicing 2 medical toxicology before there was a board 3 in the specialty, and I've been grandfathered 4 into the profession as a member of the 5 American College of Medical Toxicology. 6 Q. How long did you talk to 7 Dr. Ness about her paper? 8 A. About her paper, probably a 9 minute and a half. About all kinds of other 10 things, for a while. 11 Q. What other kinds of things? 12 A. Mostly personal things that had 13 nothing to do with talc or this case. 14 Q. How long do you think that 15 conversation was? 16 A. Well, with Dr. Ness, nothing 17 lasts very long, so I would say ten minutes 18 at the most. 19 Q. Okay. Did you call her? 20 A. No. She's -- she comes and 21 goes in the same building where I office, and 22 my office is just on the opposite side of the 23 floor of hers, and I see her sometimes in 24 passing or in the elevator.</p>	<p style="text-align: right;">Page 337</p> <p>1 A. Yes. 2 Q. And they didn't redline it or 3 make -- draw arrows or anything like that for 4 you? 5 A. I think actually George Delclos 6 did draw some -- or make some notes on there 7 and hand it back to me, and I incorporated 8 those into my electronic version. 9 Q. Do you still have George's 10 notes to you? 11 A. No, I don't. 12 Q. Is he the only one out of the 13 people that you asked to look at it who gave 14 you handwritten notes? 15 A. Yes, I think so. 16 Q. Have you seen the term 17 "intrinsic elimination system" regarding the 18 ovary in any of the publications that you've 19 read? 20 A. I don't know, I may have. 21 Q. Can you think of one in 22 particular that discusses that characteristic 23 of -- that you believe relates to the ovary? 24 A. Well, the migration papers</p>

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<p>1 discuss migration to the ovary. It would 2 probably be a talc paper, though. I don't 3 recall seeing it anywhere. 4 Q. Did you consult any gynecologic 5 textbooks? 6 A. No, I didn't. I may have 7 looked at some diagrams on the Internet. 8 Q. Okay. Did you consult any 9 gynecologic oncology textbooks? 10 A. Not textbooks, no. 11 Q. Do you know the position of the 12 Society of Gynecologic Oncologists on the 13 question of whether does talc increase a 14 woman's risk for ovarian cancer? 15 A. No, I don't. 16 Q. Would that be important to you 17 to know their position? 18 A. No, I don't think so. 19 Q. Do you know the position of 20 ACOG on whether the use of -- perineal use of 21 talc increases a woman's risk of ovarian 22 cancer? 23 A. I don't know that either. 24 That's not something I've looked at.</p>	<p>1 that? 2 A. Well, I saw this actually when 3 I first started this process, and I think 4 Dr. Longo was involved in that activity, 5 where they modeled the -- the application of 6 talcum powder and did some calculations based 7 on the amount of substance that was used, and 8 they measured it in things like shakes and -- 9 and then quantified the amount that was lost 10 from the container to determine what an 11 application amount was. 12 I don't think they were able to 13 go beyond that point in the modeling process. 14 Q. You didn't see anything that 15 Dr. Longo did that attempted to quantify the 16 amount of talcum powder from a single shake 17 that ended up on a woman's perineum, did you? 18 MS. O'DELL: Object to the 19 form. 20 A. I -- you know, I don't know the 21 answer to that, simply because I don't 22 recall, but I wouldn't be surprised that 23 there was an attempt made to do that. But 24 beyond that, I don't think anything would be</p>
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<p>1 Q. Would that be important to you? 2 A. No. 3 Q. Do you have any scientific text 4 that suggests that an inert particle resides 5 on the ovary longer than it does in the 6 cervix? 7 A. Well, I have -- I have a paper 8 that relates to the time for dissolution of a 9 particle in biological fluids, which would go 10 to the length of time a particle of talc 11 remains in the ovary once it gets there. 12 But I don't have -- I don't 13 know that I have a scientific paper that 14 specifically says that it stays in the ovary 15 longer than it stays in the cervix. 16 Q. You testified that you 17 understand there have been some attempts to 18 quantify the amount of talc, I guess from a 19 single use, that ends up on the perineum. 20 Did I understand that 21 correctly? 22 A. Yes. 23 Q. Can you tell me what those 24 attempts are, who did them, where did you see</p>	<p>1 successful. 2 These were clothed subjects, so 3 that adds another factor to the calculation. 4 BY MS. BOCKUS: 5 Q. Is that the only experiment 6 that you're familiar with that you've seen 7 anywhere that attempts to quantify the amount 8 of talcum powder from a single use that ends 9 up actually on a woman's perineum? 10 A. There was another part of that 11 study where they applied it to underwear with 12 the same sort of calculation process. It was 13 all part of the same modeling process. 14 Q. And do you recall what 15 percentage of the talc applied to the 16 underwear ended up adhered to the woman's 17 perineum? 18 MS. O'DELL: Object to the 19 form. 20 A. I don't think -- I don't think 21 they measured the amount that adhered to the 22 perineum. I think what they were interested 23 in was proximity. 24 ///</p>

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<p style="text-align: right;">Page 342</p> <p>1 BY MS. BOCKUS: 2 Q. Okay. Can you tell me the 3 names of the environmental websites that have 4 been talking about IARC revisiting their 5 classification of talc? 6 A. There are -- there are a number 7 of Twitter feeds and websites that carry on 8 this kind of discussion. Science Interest is 9 one of them. I think IARC Watch is another 10 one. I have -- I get e-mails about some of 11 these and end up going into them for a period 12 of time and seeing if they have anything 13 interesting going on. Some of them are 14 searchable. 15 And then I get e-mails from the 16 ones that I visit about other ones. So I 17 spend as much of my time deleting these 18 e-mails without reading them as I do actually 19 viewing the material. 20 Q. So fair to say this is just 21 chatter you've seen on the Internet in these 22 different chat rooms or Twitter accounts that 23 you visit from time to time? 24 A. It's all Internet based, yes.</p>	<p style="text-align: right;">Page 344</p> <p>1 A. Uh-huh. 2 Q. And echoing what my colleagues 3 have said today, if there's at any point I 4 ask a question that you do not understand, 5 just stop me and ask me to rephrase it or let 6 me know otherwise, okay? 7 A. I will. 8 Q. Thanks. 9 So going back shortly to your 10 scope of work, do you teach any coursework on 11 talc or ovarian cancer? 12 A. I teach some general courses. 13 Up until last spring I taught a general 14 environmental health course for graduate 15 students in the Master of Public Health 16 program at the School of Public Health, and 17 in that course we did touch on things like 18 environmental exposures that would include 19 minerals of various varieties, but it was 20 very cursory. 21 Q. And was that curriculum 22 specific to environmental and industrial 23 products or minerals as opposed to consumer 24 products?</p>
<p style="text-align: right;">Page 343</p> <p>1 MS. BOCKUS: Okay. I think 2 that's all I have. Thank you. 3 MS. O'DELL: Why don't we take 4 a short break. We've been going about 5 two hours. 6 MR. ZELLERS: Do you have 7 questions? 8 MS. APPEL: I do, but -- 9 MS. O'DELL: Yeah, do you 10 have -- 11 MS. APPEL: I don't have a lot. 12 MS. O'DELL: Okay. Sure. Why 13 don't you go ahead, and then we'll 14 take a break. We have been going 15 about two hours, but, Renée, please. 16 If you're okay, Doctor. 17 THE WITNESS: I'm fine. 18 EXAMINATION 19 BY MS. APPEL: 20 Q. It's been a while since we did 21 introductions, so just as a reminder, my name 22 is Renée Appel and I'm here on behalf of 23 Seyfarth Shaw and I represent Personal Care 24 Products, counsel.</p>	<p style="text-align: right;">Page 345</p> <p>1 A. We actually did touch on other 2 consumer products as well in terms of the 3 significant environmental problem that we 4 have currently, but -- regarding the huge 5 volume of personal care products that goes 6 into our aqueous waste stream and how that's 7 affecting the aquatic environment as well as 8 groundwater and so forth. 9 As a matter of fact, in that 10 course, as part of the culmination of the 11 course, there are student workgroups that 12 develop presentations on a particular topic, 13 and the topic of personal care products has 14 been a favorite choice for the last several 15 years. 16 Q. But your curriculum did not 17 include talc among those products? 18 MS. O'DELL: Object to the 19 form. 20 A. I think talc may have been 21 represented as an individual mineral on a 22 slide that listed many minerals. 23 BY MS. APPEL: 24 Q. Earlier today you had mentioned</p>

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<p style="text-align: right;">Page 346</p> <p>1 a shared file. Is that shared file something 2 that you created or plaintiffs' counsel 3 created? 4 A. It's something that I think 5 plaintiffs' counsel created for me to be able 6 to send them documents and receive documents, 7 and it's a Dropbox share file. It's -- at 8 this point I think it might be mine. I'm not 9 sure just exactly who's in charge of that or 10 runs it, but it comes directly into my 11 Dropbox file. 12 I know I had to boost my 13 subscription to Dropbox in order to hold the 14 2 gigabytes of data from -- that we were 15 putting into there. 16 Q. Is there anything from that 17 Dropbox file that you relied upon in forming 18 your opinion in your report that you have not 19 already provided to defense counsel? 20 A. No, everything that was in that 21 Dropbox that I've relied upon has been 22 identified here. 23 Q. Who prepared Exhibit B to your 24 report?</p>	<p style="text-align: right;">Page 348</p> <p>1 accumulating information in the draft as a 2 result of my review of the literature. 3 So if I had to separate things 4 out, I would say that, by far, the -- most of 5 the time has been spent in reading articles 6 and reviewing them and comparing them with 7 other articles, and a comparatively small 8 amount of time has been spent in drafting the 9 report. 10 Although there were some 11 strings of activity which was all report 12 drafting basically, I would say probably 85 13 to 90% was research, seeking articles, 14 reading them, reviewing them, and comparing 15 them. 16 Q. And you also testified earlier 17 today that you discarded information not 18 relevant or interesting to you. 19 How did you make that 20 determination? 21 MS. O'DELL: Objection to the 22 form. 23 A. The things that I discarded did 24 not seem to fit into my gestalt of the</p>
<p style="text-align: right;">Page 347</p> <p>1 A. Exhibit B was a list of 2 articles from the research literature 3 included in the Dropbox that -- that I think 4 does not -- I don't know whether it includes 5 the referenced articles from my report or 6 not, but they were all part of the same 7 collection of research articles and 8 supplemental documents. 9 Q. And my question, Dr. Carson, 10 was: Who prepared that exhibit? 11 A. The exhibit was prepared by the 12 plaintiffs' attorneys. 13 Q. You testified earlier that you 14 have spent approximately 150 to 180 hours in 15 your expert retention work; is that correct? 16 A. Correct. 17 Q. Can you estimate what portion 18 of that time was spent researching versus 19 what portion of time was spent actually 20 drafting your expert report? 21 A. Those two things are in some 22 ways difficult to separate because I would -- 23 I was writing my report the entire time that 24 I was reviewing the research materials and</p>	<p style="text-align: right;">Page 349</p> <p>1 understanding of this question and the 2 opinions that I wanted to express. They may 3 have been interesting information and useful 4 for some purposes, but not for this 5 particular report. 6 BY MS. APPEL: 7 Q. Was some of that information 8 that you discarded based on relevancy or that 9 you determined was not of interest 10 information that may have been different than 11 your opinions? 12 A. No. I didn't discard any 13 research because the opinions provided 14 differed from my own. These were things that 15 really were irrelevant to the question. 16 I remember finding an awful lot 17 of geological research stuff that just didn't 18 have any relevance to the question. 19 Because I used such broad 20 search terms, I ended up pulling in a whole 21 lot of things that were not necessary or 22 useful, and those just went in the trash. 23 Q. You testified earlier that you 24 have not treated any patients with ovarian</p>

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<p>1 cancer; is that correct?</p> <p>2 A. Not knowingly, not because of</p> <p>3 ovarian cancer.</p> <p>4 Q. Have you ever diagnosed any</p> <p>5 patients with ovarian cancer?</p> <p>6 A. I think when I was in medical</p> <p>7 school or residency, I probably participated</p> <p>8 in that on several patients.</p> <p>9 Q. Have you ever instructed a</p> <p>10 patient not to use talcum powder products?</p> <p>11 A. I hadn't up until a month or</p> <p>12 two ago, but I've been asking people about --</p> <p>13 about their talcum powder use just as sort of</p> <p>14 a curiosity in mentioning that there might be</p> <p>15 a risk.</p> <p>16 Q. Do you ask that of all your</p> <p>17 patients?</p> <p>18 A. I would say no, I don't usually</p> <p>19 ask the men that, but I probably should.</p> <p>20 Q. And have the responses to those</p> <p>21 inquiries of your female patients and their</p> <p>22 talcum product use, has that been used at all</p> <p>23 to inform your opinions in this case?</p> <p>24 A. I don't think so. There have</p>	<p>1 usually administer to my patients, and I have</p> <p>2 plans to add that as a question in my</p> <p>3 environmental exposure survey. Which I</p> <p>4 haven't done already, but will as soon as I</p> <p>5 get the opportunity.</p> <p>6 BY MS. APPEL:</p> <p>7 Q. You testified earlier today</p> <p>8 that you do not believe there was ever a</p> <p>9 point where talcum powder did not contain</p> <p>10 asbestos, correct?</p> <p>11 A. Yes.</p> <p>12 Q. So in forming your opinion in</p> <p>13 your report, you've assumed that the talcum</p> <p>14 powder does contain asbestos, correct?</p> <p>15 MS. O'DELL: Object to the</p> <p>16 form.</p> <p>17 A. Well, I think the asbestos</p> <p>18 contribution to this whole issue is important</p> <p>19 and significant. I think there's good</p> <p>20 evidence that whatever we call talcum powder</p> <p>21 is carcinogenic and responsible for ovarian</p> <p>22 cancer -- as a cause of ovarian cancer, but I</p> <p>23 can't say -- I can't say based on looking at</p> <p>24 a can of talcum powder whether or not it has</p>
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<p>1 been very few that I have asked that question</p> <p>2 in the last month or so. I've had a limited</p> <p>3 clinic schedule during this period of time.</p> <p>4 We had the holidays and other things, so I</p> <p>5 haven't seen that many patients.</p> <p>6 And of those I've asked about</p> <p>7 it, it seems about half of the women have had</p> <p>8 a history of using talcum powder.</p> <p>9 Q. And of those women that are</p> <p>10 using -- have told you that they have used</p> <p>11 talcum powder, are those women diagnosed with</p> <p>12 ovarian cancer?</p> <p>13 A. No.</p> <p>14 Q. So suffice to say the inquiry</p> <p>15 that you've asked of your female patients</p> <p>16 concerning their talcum use has nothing to do</p> <p>17 with the question that you've been posed in</p> <p>18 this particular litigation?</p> <p>19 MS. O'DELL: Object to the</p> <p>20 form.</p> <p>21 A. Actually, that's the only</p> <p>22 reason I've been asking them. It's not</p> <p>23 something that came to mind earlier. I have</p> <p>24 an environmental exposure survey that I</p>	<p>1 asbestos in it or how much.</p> <p>2 BY MS. APPEL:</p> <p>3 Q. Have you formed an opinion,</p> <p>4 Dr. Carson, on whether there's a relationship</p> <p>5 between pure talc and ovarian cancer?</p> <p>6 MS. O'DELL: Objection to form.</p> <p>7 A. My opinion is there is, but</p> <p>8 that's based on the research reports that</p> <p>9 have been done using so-called pure talc,</p> <p>10 talcum powder, and I am -- I -- my opinion is</p> <p>11 that it's unlikely that those test substances</p> <p>12 actually are pure talc.</p> <p>13 BY MS. APPEL:</p> <p>14 Q. So again, Dr. Carson, in</p> <p>15 forming your opinions, you have done so on</p> <p>16 the belief that all the talc powder products</p> <p>17 or just pure talc do, in fact, contain</p> <p>18 asbestos?</p> <p>19 MS. O'DELL: Objection to form.</p> <p>20 A. It is my opinion that all</p> <p>21 talcum powder products do contain a certain</p> <p>22 amount of asbestos, even if it's extremely</p> <p>23 small.</p> <p>24 My opinions have been formed</p>

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<p>1 based on research that has been done on 2 available talcum powder products, so I guess 3 the research would have been done using some 4 small quantity of asbestos in all of those 5 studies. 6 BY MS. APPEL: 7 Q. You also testified today, 8 Dr. Carson, that you have found in your 9 research that there is a dose-response 10 relationship between talcum powder products 11 and ovarian cancer, correct? 12 A. Well, a number of the research 13 studies, the epidemiology studies have shown 14 positive and statistically significant 15 trends. 16 Q. And those trends that you're 17 relying on, Dr. Carson, actually only relate 18 to duration and frequency, correct? 19 MS. O'DELL: Objection to form. 20 A. Yes, they do relate to duration 21 and frequency, which is the only surrogate we 22 have for dose. 23 BY MS. APPEL: 24 Q. So in forming your opinion,</p>	<p>1 classified by IARC. 2 BY MS. APPEL: 3 Q. But it's your opinion that a 4 possible carcinogen -- strike that. 5 It's your opinion that any dose 6 of a possible carcinogen can cause cancer? 7 MS. O'DELL: Objection to form. 8 A. Yes, I think there is a 9 potential for any dose of a carcinogen to 10 cause a cancer. There's also the principle 11 that the lower the dose, the less likely it 12 is, the lower the risk is for developing a 13 cancer. 14 BY MS. APPEL: 15 Q. And your opinion extends to 16 those particles that have not been identified 17 as carcinogens, but may just be possible 18 carcinogens? 19 A. I think talc has been 20 identified as a carcinogen. 21 Q. So you disagree with the IARC 22 classification? 23 A. The IARC 2B classification is a 24 carcinogenic classification.</p>
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<p>1 Dr. Carson, you have not determined a level 2 of harmful exposure to talcum powder products 3 that causes ovarian cancer? 4 A. That's correct. 5 Q. And you did not conduct a dose 6 assessment between talcum powder products and 7 ovarian cancer, correct? 8 MS. O'DELL: Objection to form. 9 A. Well, I did not conduct a 10 dose-response, but I am of the opinion that 11 there's no safe threshold for exposure to a 12 carcinogen until such a threshold is 13 identified. 14 BY MS. APPEL: 15 Q. And does that include 16 Category 2B particles as well -- 17 MS. O'DELL: Objection. 18 BY MS. APPEL: 19 Q. -- that it's a possible 20 carcinogen? 21 MS. O'DELL: Objection to form. 22 A. It includes the talc that was 23 discussed in the IARC report. Those 24 conclusions have nothing to do with how it's</p>	<p>1 Q. But you recognize and -- that 2 there are different types of categories that 3 IARC has? 4 A. Yes. 5 Q. And that -- it's that talc that 6 does not contain asbestos was not, in fact, 7 categorized as a Group 1, correct? 8 A. That's correct. 9 Q. So is it your opinion, then, 10 looking at other 2B-classified particles by 11 IARC, that any exposure to pickled vegetables 12 would cause cancer? 13 A. We know that there are a number 14 of carcinogens that are regularly present in 15 things like the food that we eat. We have a 16 rule that says that those things should not 17 be included in food items unless they have 18 passed a particular exemption process. 19 Pickled vegetables are 20 something that people have been familiar with 21 and have been using for hundreds of years, 22 and things like talcum powder are things that 23 have been used for -- well, at least a 24 hundred years, but probably considerably</p>

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<p style="text-align: right;">Page 358</p> <p>1 longer.</p> <p>2 And whether or not those things</p> <p>3 are carcinogens, there are people who still</p> <p>4 find enough value to offset that factor in</p> <p>5 their own lives and they can make their own</p> <p>6 decisions regarding their exposure.</p> <p>7 It's a similar concept to</p> <p>8 people who choose to smoke. Although smoking</p> <p>9 is an addictive behavior, people are aware</p> <p>10 that it causes disease, including cancer, and</p> <p>11 yet they continue to smoke.</p> <p>12 We continue to eat grilled</p> <p>13 meats, even -- most of us know now that</p> <p>14 grilled meats contain polycyclic aromatic</p> <p>15 hydrocarbons that are known carcinogens, some</p> <p>16 of them Group 1 carcinogens, and yet, we</p> <p>17 continue that practice and revel in it even.</p> <p>18 That's just part of what we do as human</p> <p>19 beings.</p> <p>20 The issue with talc is a</p> <p>21 complicated question in my mind. I think I'm</p> <p>22 straying a bit from your -- from your</p> <p>23 question, but baby powder, for example, is</p> <p>24 something that has a very -- very dear sort</p>	<p style="text-align: right;">Page 360</p> <p>1 A. Pickled vegetables.</p> <p>2 Q. -- I had was pickled</p> <p>3 vegetables, and the question was whether or</p> <p>4 not is your opinion that any consumption of</p> <p>5 pickled vegetables causes cancer?</p> <p>6 MS. O'DELL: Objection to form.</p> <p>7 A. I believe the primary form of</p> <p>8 cancer that's potentially related with</p> <p>9 pickled vegetables is stomach cancer, and</p> <p>10 there is a slight increase in risk with</p> <p>11 consumption of pickled vegetables for</p> <p>12 everybody who does it.</p> <p>13 BY MS. APPEL:</p> <p>14 Q. Okay. And what about gasoline</p> <p>15 or exhaust?</p> <p>16 A. Gasoline meaning the fuel?</p> <p>17 Q. Yes.</p> <p>18 A. Well, gasoline used to contain</p> <p>19 a significant amount of benzene, which was</p> <p>20 a -- determined to be a carcinogenic</p> <p>21 substance. In recent years, most of the</p> <p>22 benzene has been removed from gasoline, so</p> <p>23 now there's very little benzene in vapors</p> <p>24 that are expressed.</p>
<p style="text-align: right;">Page 359</p> <p>1 of relationship to many people.</p> <p>2 The experience with that from</p> <p>3 the time you were a baby until you grow up</p> <p>4 and have your own children involves a lot of</p> <p>5 the use of baby powder in many, many</p> <p>6 households. That's a difficult relationship</p> <p>7 to break. It's psychological as much as it</p> <p>8 is knowledge based.</p> <p>9 So as we go through the</p> <p>10 decades, we get a little safer and safer as</p> <p>11 we begin to peel these habits, these</p> <p>12 dangerous habits away from our lives and</p> <p>13 accept better lifestyles.</p> <p>14 MR. ZELLERS: Move to strike as</p> <p>15 nonresponsive.</p> <p>16 MS. APPEL: Respectfully --</p> <p>17 MS. BOCKUS: Is he finished?</p> <p>18 MR. ZELLERS: I don't think so.</p> <p>19 THE WITNESS: I can go on.</p> <p>20 BY MS. APPEL:</p> <p>21 Q. Yeah. My question was more</p> <p>22 narrow, and I was analogizing your opinion as</p> <p>23 to talcum powder and was asking about other</p> <p>24 2B classifications, and my example --</p>	<p style="text-align: right;">Page 361</p> <p>1 But there's a small amount. So</p> <p>2 when you inhale gasoline vapors, you are also</p> <p>3 exposing yourself to a very small amount of a</p> <p>4 carcinogenic substance.</p> <p>5 As far as exhaust is concerned,</p> <p>6 diesel exhaust in particular has -- contains</p> <p>7 particles that have been identified through</p> <p>8 various bioassays to be carcinogenic. So</p> <p>9 diesel exhaust is regulated as a carcinogenic</p> <p>10 material, even though we continue to be</p> <p>11 exposed.</p> <p>12 Q. And it's your opinion that any</p> <p>13 exposure that we all incur related to exhaust</p> <p>14 will cause us cancer?</p> <p>15 MS. O'DELL: Objection to form.</p> <p>16 A. It will cause an increase in</p> <p>17 risk of cancer. Doesn't necessarily cause</p> <p>18 cancer in everybody.</p> <p>19 BY MS. APPEL:</p> <p>20 Q. Okay. Are you aware that Saed</p> <p>21 has been hired by plaintiffs' counsel in this</p> <p>22 litigation?</p> <p>23 A. I am. And when I misspoke</p> <p>24 earlier today regarding the Taher paper, I</p>

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<p style="text-align: right;">Page 362</p> <p>1 was thinking of the Saed paper.</p> <p>2 Q. Okay. Last question: Counsel</p> <p>3 was asking you about the migration process,</p> <p>4 and you mentioned that in the course of</p> <p>5 particles moving up the track, that some of</p> <p>6 it may come back out even after it reaches</p> <p>7 the fluid surrounding the ovaries, correct?</p> <p>8 A. Yes.</p> <p>9 Q. So if particles have the</p> <p>10 ability to come back out, that means that</p> <p>11 there is, in fact, some form of an intrinsic</p> <p>12 elimination system.</p> <p>13 A. Well, if this is all based on</p> <p>14 mass action, it would not necessarily be an</p> <p>15 intrinsic elimination system, and I believe</p> <p>16 that talc particles, once they produce an</p> <p>17 inflammatory response, they become</p> <p>18 sequestered within that inflammatory milieu</p> <p>19 and no longer are available for movement back</p> <p>20 out into the fluid.</p> <p>21 I'm sure there's some small</p> <p>22 percentage of them that are an exception to</p> <p>23 that, but for the majority, that would be the</p> <p>24 case.</p>	<p style="text-align: right;">Page 364</p> <p>1 CERTIFICATE</p> <p>2 I, MICHAEL E. MILLER, Fellow of</p> <p>3 the Academy of Professional Reporters,</p> <p>4 Registered Diplomate Reporter, Certified</p> <p>5 Realtime Reporter, Certified Court Reporter</p> <p>6 and Notary Public, do hereby certify that</p> <p>7 prior to the commencement of the examination,</p> <p>8 ARCH I. "CHIP" CARSON, M.D., Ph.D. was duly</p> <p>9 sworn by me to testify to the truth, the</p> <p>10 whole truth and nothing but the truth.</p> <p>11 I DO FURTHER CERTIFY that the</p> <p>12 foregoing is a verbatim transcript of the</p> <p>13 testimony as taken stenographically by and</p> <p>14 before me at the time, place and on the date</p> <p>15 hereinbefore set forth, to the best of my</p> <p>16 ability.</p> <p>17</p> <p>18 I DO FURTHER CERTIFY that pursuant</p> <p>19 to FRCP Rule 30, signature of the witness was</p> <p>20 not requested by the witness or other party</p> <p>21 before the conclusion of the deposition.</p> <p>22 I DO FURTHER CERTIFY that I am</p> <p>23 neither a relative nor employee nor attorney</p> <p>24 nor counsel of any of the parties to this</p> <p>action, and that I am neither a relative nor</p> <p>employee of such attorney or counsel, and</p> <p>that I am not financially interested in the</p> <p>action.</p> <p>MICHAEL E. MILLER, FAPR, RDR, CRR</p> <p>Fellow of the Academy of Professional Reporters</p> <p>NCRA Registered Diplomate Reporter</p> <p>NCRA Certified Realtime Reporter</p> <p>Certified Court Reporter</p> <p>Notary Public in and for the</p> <p>State of Texas</p> <p>My Commission Expires: 7/9/2020</p> <p>Dated: January 22, 2019</p>
<p style="text-align: right;">Page 363</p> <p>1 MS. APPEL: Okay. That's all I</p> <p>2 have. Thank you, Dr. Carson.</p> <p>3 MS. TINSLEY: I don't have any</p> <p>4 questions.</p> <p>5 MS. O'DELL: Okay. Why don't</p> <p>6 we take a short break.</p> <p>7 THE VIDEOGRAPHER: Off the</p> <p>8 record at 5:37, end of Tape 4.</p> <p>9 (Recess taken, 5:37 p.m. to</p> <p>10 5:44 p.m.)</p> <p>11 THE VIDEOGRAPHER: We're on the</p> <p>12 record at 5:44, beginning of Tape 5.</p> <p>13 MS. O'DELL: Dr. Carson, I</p> <p>14 don't have any questions, so this will</p> <p>15 conclude your deposition.</p> <p>16 MR. ZELLERS: Thank you,</p> <p>17 Doctor.</p> <p>18 THE VIDEOGRAPHER: Going off</p> <p>19 the record, 5:44. End of deposition,</p> <p>20 end of Tape 5.</p> <p>21 (Proceedings recessed at</p> <p>22 5:45 p.m.)</p> <p>23 --o0o--</p> <p>24</p>	<p style="text-align: right;">Page 365</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the</p> <p>6 appropriate space on the errata sheet for any</p> <p>7 corrections that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it.</p> <p>10 You are signing same subject to</p> <p>11 the changes you have noted on the errata</p> <p>12 sheet, which will be attached to your</p> <p>13 deposition.</p> <p>14 It is imperative that you return</p> <p>15 the original errata sheet to the deposing</p> <p>16 attorney within thirty (30) days of receipt</p> <p>17 of the deposition transcript by you. If you</p> <p>18 fail to do so, the deposition transcript may</p> <p>19 be deemed to be accurate and may be used in</p> <p>20 court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<div style="text-align: right; padding-right: 20px;">Page 367</div> <div style="text-align: center;">ACKNOWLEDGMENT OF DEPONENT</div> <p>I, ARCH I. "CHIP" CARSON, M.D., Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.</p> <div style="text-align: center;">_____</div> <div style="text-align: center;">ARCH I. "CHIP" CARSON, M.D., Ph.D. DATE</div> <p>Subscribed and sworn to before me this _____ day of _____, 20 ____.</p> <p>My commission expires: _____</p> <div style="text-align: center;">_____</div> <div style="text-align: center;">Notary Public</div>	

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Exhibit 5

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

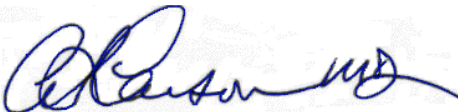
**IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION**

MDL NO. 16-2738 (FLW) (LHG)

THIS DOCUMENT RELATES TO ALL CASES

**RULE 26 EXPERT REPORT OF
ARCH CARSON, MD, PHD**

Date: November 16, 2018



Arch Carson, MD, PhD

Talcum Powder and Ovarian Cancer

1. Introduction

I was asked to explain the relationship between the regular perineal use of talc-based personal hygiene products and the subsequent development of ovarian cancer in their users. I intend this report to explain this relationship. I will describe ovarian cancer, what is known about its natural history, and will present statistics regarding its incidence, prevalence and fatality. I will then describe what talc is and why talcum powder is used in personal care products. I will then present the scientific evidence linking talc-based personal hygiene products and their components with cancer, and will show how the various components of this evidence, along with other data, lead me to conclude that regular perineal application of talcum powder products causes ovarian cancer in some users, and raises the risk of ovarian cancer in all users.

2. Qualifications

I am a physician who specializes in the practice of medical toxicology. I am currently an Associate Professor at the University of Texas School of Public Health in Houston and the Program Director of the Occupational and Environmental Medicine Residency training program at the University of Texas Health Science Center at Houston. I received my medical degree from the Ohio State University and a doctor of philosophy degree in Toxicology from the Kettering Laboratory at the University of Cincinnati. I am board certified by the American Board of Preventive Medicine in Occupational Medicine, and have been in the continuous practice of medical toxicology since 1991. My professional activities have included patient care, basic and applied research, teaching of medical students, graduate students and post-graduate medical trainees, and professional consulting. I have been a program director of the NIOSH-funded Education and Research Center at the University of Texas for 19 of the last 21 years. Other major collaborations include as Liaison for the World Health Organization Collaborating Centre in Occupational Health and as environmental exposure consultant to the MD Anderson Cancer Center in Houston. My curriculum vitae is attached to this report as Exhibit A.

3. Information reviewed and methodology employed

In the preparation of this report, I have reviewed relevant published scientific and medical literature, reports and documents produced in the process of litigation, and various other documents and websites that I believed to be pertinent to the refinement or extension of my professional opinions. I applied the same methodology and scientific rigor in this research that I use in my academic and clinical practice. Documents and other sources which I considered in reaching my opinions are listed in Exhibit B, "Materials and Data Considered."

4. What is ovarian cancer?

a. What is cancer?

All types of cancer involve the uncontrolled growth and accumulation or dissemination of cells that originated from normal cells, but have been altered so that they behave differently. The many cells of a single cancer that result from this change are typically all derived from a single progenitor cell, and represent a clone of cells. When this clone

reaches sufficient numbers, the cells themselves may develop into a recognizable “mass” that is called a tumor. Tumors may cause symptoms and other health problems simply by taking up space and putting pressure on neighboring structures or blocking important fluid channels or nerves, thus disrupting normal functions of the body. Still other cancers can proliferate into the blood stream. As the number of cancerous cells increase, the biochemically active substances that they produce can also become a problem resulting in abnormal biological responses throughout the body. Some substances that might become a problem in this way include normal or abnormal hormones, enzymes, antibodies, and proteins. Cancerous cells are considered malignant if they lose their normal tendency to stop proliferating when they have filled a space or the bounds of their particular tissue type, referred to as contact inhibition. Malignant cells ignore these boundary cues and may invade other tissue spaces and organs with devastating results. They may also migrate via the blood stream or other routes to distant sites within the body where they set up a new location of tumor growth and tissue invasion. This process is called metastasis. Typically, cancers are not diagnosed until they produce sufficient symptoms or biochemical abnormalities that lead to an exhaustive diagnostic search resulting in their discovery. Occasionally, cancers are discovered accidentally as part of another investigation, e.g. a chest x-ray may find an asymptomatic lung cancer; a blood test may disclose a telltale abnormality. Still fewer cancers are discovered before they cause health problems through screening tests that are sensitive and specific enough to detect common cancers at a preclinical and hopefully highly treatable stage, e.g. routine colonoscopies to detect colon cancer, or PSA blood tests to detect prostate cancer.

b. Carcinogenesis-a two-step process

The process of normal cells becoming cancer cells is generally recognized as resulting from a two-step process.

Initiation. During initiation, a change is produced at one or more places in the DNA of a cell’s chromosomes. Because the DNA represents the genetic code that becomes duplicated and passed along to cells that arise from it, when that cell divides to produce two cells, the change to the genetic code is also duplicated and is present in both of them.

Normally, the abnormal cell that results from a change in the genetic code cannot survive because its cellular machinery is also abnormal and poorly or non-functional. Less often, if the cell is able to survive in the body, it is still abnormal and deformed, and is recognized by the body’s immune system as alien. The immune system attacks it and destroys it, and it does not survive. In the very rare instance that an alteration to the genetic material results in a survivable hereditary change that is not fatal, and which can escape the surveillance of the body’s immune system, the resulting clone may live and persist. (Coussens LM, 2002)

Promotion - Once a cancer clone has been produced, it is at risk for being discovered and destroyed by the body’s immune system, or failing to thrive in an environment for which it is not suited. Promotion is the process by which the cancer clone is shielded

from the body's defenses and is stimulated to undergo rapid growth, transforming a microscopic cancer clone into a self-sustaining symptomatic cancer over time. (Ferrante D, 2007) (Coussens LM, 2002)

Most known carcinogenesis events occur by the two-step process and involve a long latent period between the moment of the alteration in the genetic material and the recognition that a cancer is present. In human cancers, this latent period is often several months to many years in length. The latency period for ovarian cancer, generally, and for cancers induced by environmental agents is usually quite long, often >20 years. (Nadler DL, 2014) Promotion occurs throughout the latent period and stimulates the growing cancerous cells to become a recognizable cancer. A third stage in the natural history of a cancer, referred to as Progression, involves maturation, differentiation or de-differentiation and accumulation of transcriptional changes that solidify the tumor's growth rate and invasiveness. Some carcinogenic substances are initiators and some are promoters, and still others are called complete carcinogens because they are capable of initiation and promotion.

c. Ovarian cancer

Ovarian cancer is a group of cancers that arise in the ovary or in adjacent tissues. It is estimated that about 22,240 women will receive a new diagnosis of ovarian cancer and about 14,070 women will die from ovarian cancer in the United States in 2018. (American Cancer Society, n.d.) (Torre LA, 2018) Ovarian cancer ranks fifth in cancer deaths among women, and first due to cancers of the female reproductive system. Most ovarian cancers are not discovered until they have reached an advanced stage and have spread to sites elsewhere in the body. Because advanced ovarian cancers are more difficult to treat, they have a high fatality rate. For these reasons, any effective prevention of ovarian cancer or reduction in ovarian cancer risk can have a significant impact on this disease and can save many women's lives.

There are several recognized forms of ovarian cancer that are distinguished by the specific tissues from which they arise, or the microscopic characteristics of the tumor cells themselves. About 85% to 90% of malignant ovarian cancers are epithelial ovarian carcinomas, and the majority of these are of the serous type (American Cancer Society, n.d.) (Prat, 2015). Ovarian, fallopian tube, and peritoneal cancers have a similar clinical presentation and are treated similarly, and current evidence suggests that they may have a common origin, supporting a common staging system (Soong TR, 2018).

Despite significant advances in cancer diagnosis and therapies over the past several decades, there have been few changes in the incidence or fatality rates for ovarian cancer. Consequently, it is worth considering preventable environmental causes of the ovarian cancer epidemic. (Woodruff, 1979) (LA Torre, 2018)

5. What is talc?

a. General

Talc is a hydrated magnesium silicate mineral produced through a metamorphic geological process and having the generalized chemical formula $\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$. Some substitution of atoms occurs in variations of talc found in nature. Small amounts of Aluminum (Al) or Titanium (Ti) can substitute for Silicon, and small amounts of Iron (Fe), Manganese (Mn), Aluminum (Al) and Calcium (Ca) can substitute for Magnesium. This produces slight variations in the color, hardness and chemical properties of the mineral. Talc is the softest mineral on the Mohs Hardness Scale. (King, n.d.) It is essentially insoluble in water, but is slightly soluble in dilute mineral acids. The process seems to involve the extraction of magnesium and other cations leaving only the silicate as silicic acid and silica.

The commercial value of talc stems from its crystalline structure. Most talc is present in natural deposits as the platy form of talc, in which the talc crystals are arranged in large flat sheets running parallel to one another. These sheets are attracted to each other by weak Van der Waals forces that can be easily overcome by mechanical forces, causing the sheets to slide on each other. On the macro scale, this property gives talc its characteristic slippery feeling on the skin. The platy structure also gives talc its ability to absorb moisture and oil. Some talc is found as a fibrous crystalline structure, similar to some asbestos, also a magnesium silicate mineral. In fact, these two minerals are closely related in terms of their formation and composition. Talc deposits are often intermingled with asbestos and vice versa. (Rohl, 1974) (Rohl AN, 1976) (National Institute for Occupational Safety and Health, 2011) (Lockey, 1981)

b. Talcum Powder and Cancer.

Numerous studies have examined the cancer causing characteristics of talc. (Wild, 2006) Talc has caused cancer when implanted in various tissues and under the skin in laboratory animals. It causes inflammation and fibrotic reaction, including the chemotaxis of inflammatory immune cells, and accelerated growth and division of cells in the involved tissues (Okada, 2007). This is a normal body process that leads to the thwarting of infection and rapid healing, but in the absence of tissue injury, accelerated growth and cell division has the effect of amplifying and propagating viable genetic mutations, leading to cancer. Talc particles have been repeatedly demonstrated in ovarian tumor tissues (Henderson WJ C. J., 1971) (Henderson WJ T. H., 1979) and in inflammatory tissue in otherwise normal ovaries (Mostafa SAM, 1985). In 2006, the International Agency for Research on Cancer (IARC) evaluated the published evidence for the carcinogenicity of talc, not containing asbestiform fibers, when inhaled into the respiratory system and when applied to the perineum in personal hygiene activities. The agency concluded that talcum powder is a “possible human carcinogen” (Group 2B) when applied to the perineum, meaning that there is insufficient evidence of carcinogenesis in humans, but strong evidence in other mammalian species. IARC also concluded that there was insufficient evidence of carcinogenicity by the inhalation route (Group 3). (International Agency for Research on Cancer, 2010) Since that time,

numerous other studies have added to the data on this issue. A recent meta-analysis showed that talc workers do have an excess of lung cancers. (Chang C-J, 2017)

When implanted under the skin or into tissues of laboratory animals, talcum powder induces an inflammatory response. This reaction involves the chemotaxis of inflammatory cells of the immune system, lymphocytes, neutrophils and macrophages, the release of cytokines that promote membrane permeability and stimulate cell division. As this reaction matures over time, granulomas may begin to develop. All of this signifies that talcum powder is an effective and potent promotor of already initiated genetic alterations. (Fletcher NM M. I., 2018) (Fletcher NM S. G., 2018) (Saed GM, 2017) (Radić I, 1988) (Okada, 2007) Other studies have demonstrated the ability of these same reactions to satisfy the carcinogenic initiation step, characterizing talcum powder as a complete carcinogen. (Shukla A, 2009) (Fletcher NM M. I., 2018)

c. What about asbestos and other components in talc and talc-based products?

Talcum powder products in the marketplace have been shown to contain asbestos. (Paoletti L, 1984) (VanOrden D, 2000) (VanGosen BS, 2004) (Longo WE, 2017) Asbestos is conclusively recognized as a cause of ovarian cancers. The IARC Working Group concluded that “a causal association between exposure to asbestos and cancer of the ovary was clearly established, based on five strongly positive cohort mortality studies of women with heavy occupational exposure to asbestos, (International Agency for Research on Cancer, 2012)” and “studies showing that women and girls with environmental, but not occupational exposure to asbestos had positive, though non-significant, increases in both ovarian cancer incidence and mortality. (Acheson ED, 1982) (Fox, 1982) (Berry G, 2000) (Newhouse ML, 1972) (Reid A H. J., 2008) (Reid A S. A., 2009) (Pira E, 2005) (Magnani C, 2008) (Bertolotti M, 2008) (Ferrante D, 2007) (Germani D, 1999) (Rösler JA, 1994) The classification determined by IARC included all forms of asbestos and talc containing asbestiform fibers (fibrous talc). I have seen evidence that Johnson & Johnson’s talcum powder products contain asbestos and fibrous talc.¹

d. Carcinogenic metals in talcum powder

In addition to other related minerals, talcum powder may contain varying amounts of chromium, cobalt and nickel, metal ions that are recognized as cancer causing. These ions leach out of the talcum powder slowly over time, resulting in continuous, low-level exposure of the surrounding tissues to carcinogenic metals. (Jurinski JB, 2001) I have seen evidence that Johnson & Johnson’s talcum powder products contain nickel (Group 1

¹ Ex. 28, Hopkins Dep. (Aug. 16 & 17, 2018; Oct. 26, 2018; and Nov. 5, 2018); Ex. 47, Pier Dep. (Sept. 12 & 13, 2018); Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD (Nov. 14, 2018)

human carcinogen), chromium (Group 1 human carcinogen), and cobalt (Group 2B-possible human carcinogen).²

e. Other potentially cancer-causing constituents

Johnson & Johnson's Baby Powder and Shower to Shower contain numerous ingredients that have been added to the products, i.e. fragrance chemicals, some of which have been shown to produce cancer in laboratory animals. These substances are likely to be present in very small or trace quantities, and likely present a lower level of risk than the major components, by mass. Nonetheless, any additional risks are added as part of a total risk profile. I have reviewed the report of Dr. Michael Crowley and agree with his conclusions that these chemicals may contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products.³

6. Epidemiology linking talcum powder and ovarian cancer

Many research studies have shown a strong association between talcum powder exposure and the development of ovarian cancer. (Langseth H, 2008) (Terry KL, 2013) (Schildkraut JM, 2016) (Trabert, 2016) (Berge W, 2017) (Cramer Daniel W, 2016) (Penninkilampi R, 2018)

a. What evidence links exposure to talcum powder products with ovarian cancer?

Multiple epidemiological studies have examined the link between the personal hygiene use of talc containing products and the occurrence of ovarian cancers (Booth M, 1989) (Cook LS K. M., 1997) (Cook LS e. a., 1997) (Cramer DW, 1982) (Whittemore AS, 1988) (Harlow BL W. B., 1989) (Chen Y, 1992) (Harlow BL C. D., 1992) (Rosenblatt KA, 1992) (Hartge P, 1988) (Tzonou A, 1993) (Chang S, 1997) (Heller DS, 1996) (Penninkilampi R, 2018). Talcum powder causes proliferation of human (Prat, 2015) ovarian cells in culture (Buz'Zard AR, 2007), and causes these cells to express reactive oxygen species (ROS) (Buz'Zard AR, 2007).

The research investigating the link between talcum powder exposure and ovarian cancer has been reviewed as a scientific whole at multiple stages. (Harlow BL H. P., 1995) (Ness Roberta B, 1999) (Muscat JE, 2008) (Terry KL, 2013) (Berge W, 2017) (Penninkilampi R, 2018)

Laboratory, animal and human studies support the conclusions that talc causes ovarian cancer, and have filled in the blanks that establish biological plausibility and scientific coherence. (Jaiswal M, 2000) (Balkwill Fran, 2001) (Okada, 2007) (Saed Ghassan M, 2017) (Harper, 2019)

7. Talcum powder product use

² Ex. 47, Pier Dep. (Sept. 12 & 13, 2018)

³ Expert Report of Michael Crowley, PhD (Nov. 12, 2018).

Numerous studies have interviewed women regarding their personal practices of application of talc-based powders to the perineal area. Due to variations in these practices, it has been difficult to estimate dose in order to evaluate the dose response relationship for ovarian cancer. It is also difficult to exactly estimate the quantity of talcum powder administration during personal hygiene activities. For studies that attempted to determine amount of exposure, most relied on a method of estimating the frequency of application and/or the duration of those practices, then simply multiplying to reach a total number of applications over time. (Harlow BL H. P., 1995) (Langseth H, 2008) A review of studies of perineal talcum powder or cornstarch application suggests that the use of cornstarch instead of talcum powder reduces the risk of ovarian cancer. (Whysner J, 2000)

8. Other evidence

- a. Transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity and with respect to a wide variety of particulate materials. (Egli GE, 1961) (Venter PF, 1979) (Blumenkrantz MJ, 1981) (Halme J, 1984) (Sjösten ACE, 2004) Clearly, sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biological responses in internal tissues, including the ovaries and surrounding structures. There are a limited number of animal studies suggesting that this transport does not occur. (National Toxicology Program, 1993) These are not as compelling as the human evidence because of anatomical and physiological differences between animals and humans in this regard, as well as the overwhelming evidence in humans.

9. Conclusions and opinions

The following conclusions and opinions are expressed with respect to reasonable medical and scientific certainty and I have applied reliable scientific principles and methods to the facts in reaching them. These opinions are based upon the documents and literature reviewed and cited herein, and also upon my own professional training and experience in practice of medicine and medical toxicology.

I. Talcum powder products sold for personal hygiene use are carcinogenic.

Talcum powder is immunogenic, producing chronic inflammation in the tissues in which it sequesters, with the attraction of lymphocytes and macrophages and the ongoing local release of pro-inflammatory cytokines and reactive oxygen species. Further, all talcum powder has some component of mineral fibers that are toxic to macrophages and intensify the inflammatory response and stimulate cell growth and proliferation. The presence of asbestos, fibrous talc, carcinogenic metals and other chemicals further intensify this effect. Cohort and case-control studies have shown statistically significant associations between talc-based powder use and ovarian cancers. The presence of carcinogenic metals such as, chromium, cobalt and nickel, and toxic fragrance components in commercial talcum powder products, adds to their carcinogenic potency. Talcum powder is a complete carcinogen and can both initiate and promote the development of cancers in the tissues in which it sequesters.

II. Perineal use of talcum powder products for feminine hygiene purposes results in direct exposure to the female reproductive tract.

A proportion of talcum powder from personal hygiene applications to the perineum is transported or migrates through the reproductive tract, through the patent fallopian tubes, onto the ovaries and into the pelvic cavity. Talc particles have been identified in reproductive system structures of women who utilize talc powders. These include the uterine cervix, the endometrium, the fallopian tubes and the ovaries. Inhalation is likely a secondary route of exposure.

III. Common carcinogenic constituents of talcum powder products participate in and add to the carcinogenic process.

Naturally occurring carcinogenic components of talcum powder, i.e. asbestos, chromium, nickel, and cobalt, are liberated in bodily fluids and tissues and are free to exert their carcinogenic effects. Added substances that are toxic or carcinogenic, i.e. fragrance chemicals, may also contribute to these effects. This process is the most intense where the duration is the longest. Because the ovaries have no intrinsic elimination system, the transport of talc particles and their constituents reaches the ovaries where it stalls and sequesters. For these reasons, ovarian tissue is most at risk for the carcinogenic effect of these substances.

IV. Regular perineal application of talcum powder products causes epithelial ovarian cancer in some users, and raises the risk of ovarian cancer in all users.

Multiple case-control and cohort epidemiological studies have looked at the relationship between the perineal use of talc-based powders and the eventual development of epithelial ovarian cancer. Most, but not all, of these studies show a consistent positive relationship. When confounding and bias are exhaustively considered, the positive association remains. I conclude that the apparent cause and effect relationship between perineal talcum powder use and ovarian cancer is real, amounting to about a 30% increased risk of ovarian cancer in talcum powder product users. At the current rate of ovarian cancer diagnosis and mortality, elimination of this source of risk could result in over 3,000 lives saved in the U.S. each year.

In 1965, Sir Austin Bradford Hill published what has come to be recognized as the best collection of factors to consider for the assessment of scientific evidence that relates the causation of disease to environmental exposures (Hill, 1965). These factors include: (1) Strength of association, (2) Consistency of the evidence, (3) Specificity, (4) Temporality, (5) Biological gradient, (6) Plausibility, (7) Coherence, (8) Experiment, and (9) Analogy. Below I provide my evaluation of the scientific evidence with respect to the Hill factors.

Strength of association –Many epidemiological studies have attempted to examine the association between perineal use of talcum powder products and ovarian cancer. Most of these have been case-control studies, where women diagnosed with ovarian cancer are paired with others of similar demographic background who do not have ovarian cancer. All of these women are interviewed about their past practices and exposures, including the use of talcum powder products. The resulting data are analyzed to compute an odds ratio (OR) that describes the

likelihood of those with cancer having had greater exposure to talcum powder than those who did not. Cohort studies selected populations of women, assessing them for many factors, including perineal talcum powder use, and followed them over time counting the occurrences of ovarian cancers. These studies were then able to compute a relative risk (RR) of exposure to talcum powder resulting in ovarian cancers. Of more than 25 case-control studies in the literature, the heavy majority showed positive and significant ORs for perineal talcum powder use and ovarian cancer. The three cohort studies did not find a significant relative risk of perineal talcum powder exposure leading to ovarian cancer, but did show positive non-significant trends. Several research groups have looked at the totality of the research evidence, evaluated the published study reports, and have reanalyzed those data on a common playing field through meta-analyses. Taken in their totality, and accounting for sources of bias and differing statistical treatments, these epidemiological studies support a strong association between the perineal use of talcum powder and ovarian cancer.

Consistency of the evidence – As stated above, the majority of epidemiological studies that have investigated the link between perineal talcum powder use and ovarian cancer have reported positive associations. These studies are consistent in their findings of a relationship between perineal use of talcum powder products and the development of ovarian cancer. Further, recent meta-analyses of previously published studies have verified the comparability of the research methods used and the consensus of conclusions.

Specificity – Specificity is the concept that a specific disease, rather than a host of diseases, is produced by a particular exposure, and that the exposure is a principal cause of the disease. Although talcum powder is known to cause non-specific inflammation in many tissues where its residues locate, the stimulation of ovarian cancer is particularly associated with the presence of talc in the ovaries and fallopian tubes. Of known factors associated with ovarian cancer, i.e. nulliparous state, early menarche, late menopause, oral contraceptive use, living in the twentieth century and beyond, perineal talcum powder exposure is proving to be prominent among them.

Temporality – If a particular exposure is the cause of a particular disease, then the onset of exposure should precede the onset of the disease. Studies investigating the link between perineal talcum powder exposure and ovarian cancer are designed to compare those with prior exposure to those who are not exposed, and so the scientific evidence supports this consideration.

Biological gradient – A basic toxicological principle is that a greater exposure intensity will result in a larger proportion of those exposed expressing the toxic effect, in this case ovarian cancer. In order to determine the intensity of a long-term environmental exposure, typically a measure of frequency or quantity of use is multiplied by the duration of such use. This allows categorization of exposure levels and comparisons. Although some studies have failed to find evidence of a dose-response relationship, several more recent reports have shown a clear dose-response when the number of subjects rose to a level producing sufficient statistical power to allow the analysis after subdivision of subjects into pertinent categorical groups, and frequency and duration were measured (Schildkraut JM, 2016) (Cramer Daniel W, 2016) (Wu, et al., 2009).

Plausibility – This factor expects the rational presentation of a mechanism whereby the exposure in question leads to the disease. Thus, if no such mechanism can be proposed, it is less likely that causation will be supported. In the case of ovarian cancer, the mechanism supported in the literature is as follows: Talcum powder products are applied to the perineal area in the course of routine personal hygiene practices. This element is supported by the existence of these products in the marketplace for many years and the statements of subjects interviewed for the purpose of conducting the scientific research discussed elsewhere in this report. Portions of the applied powders are transferred via active processes or passive mass action movements into the female reproductive tract, some making it all the way to the distal fallopian tubes, the ovary surfaces and the pelvic and peritoneal cavities. This element is supported by the observations that particulate materials of differing variety can make their ways along these pathways to the listed destinations, and the finding and confirmation of talc particles in normal ovarian tissues and ovarian tumor tissues at the time of oophorectomy or autopsy. Once reaching the target tissues, talcum powder and its constituents initiate carcinogenesis via multiple means, including, inflammation with chemotaxis of inflammatory cells, liberation of cytokines, and reactive oxygen species, inactivation of TP53 genetic modulator, inhibition of DNA repair, and long-term promotion of genetic mutations via continuous inflammation and cellular growth stimulation.

Coherence – The proposed cause and effect relationship should not “seriously conflict with the generally known facts of the natural history and biology of the disease.”(Hill, 1965) The proposal that talcum powder product use results in the occurrence of ovarian cancer is entirely consistent with what is known about other factors related to ovarian cancer, i.e. early menarche, late menopause, pregnancies, breastfeeding history, oral contraceptive use, etc. All are factors that influence the local inflammatory environment of the ovary and its surroundings and have the potential to promote existing transcriptional errors and mutations.

Experiment – Interventions, such as tubal ligation that decreases the incidence of ovarian cancer by blocking the exposure route, offers experimental support for this mechanism. The use of cornstarch-based dusting powders as a substitute for talcum powder products offers additional experimental support.

Analogy – Have there been other environmental exposures that have been associated with ovarian cancers that act via similar mechanisms? Talcum powder is somewhat unique in terms of its delivery mechanism. But beyond that, the case of asbestos exposure is similar. Asbestos exposure has resulted in excesses of ovarian cancers in exposed women, although the route of exposure is thought to be by inhalation. Nonetheless, asbestos is a mineral very similar both chemically and structurally to talc that has been found in the ovary and peritoneal cavity of exposed women. The mechanisms of carcinogenesis for both asbestos and talc are similar and analogous. Further, talc-based products contain asbestos and non-asbestos mineral fibers having carcinogenic potential.

When considering these factors, I gave the most weight to the compelling strength of association and consistency, as well as the well-described biologic mechanism.

The currently available scientific research, when considered in its totality, demonstrates a cause and effect relationship between the use of talcum powder products and the development of epithelial ovarian cancer. This opinion is reinforced by my consideration of the Hill factors for the assessment of causation.

In reviewing the scientific and medical literature on talcum powder product use, I also performed a risk assessment and considered whether perineal use of those products poses a safety risk to consumers. This involved careful consideration of the epidemiological literature, data on the dose-response relationship and exposure, as well as the nature of these products, which are used primarily for personal care. I also considered evidence of the toxicity of these products, for which repeated testing and analyses have shown to contain carcinogens.

In considering the weight of this epidemiologic, toxicologic, and mechanistic evidence, across multiple studies, time, demographics, and researchers, demonstrating a consistent association between perineal use of talcum powder products and ovarian cancer, it is my opinion that talcum powder products increase the risk of ovarian cancer and pose a significant health hazard.

In conclusion, it is my opinion that the perineal use of talcum powder products causes ovarian cancer in some users and increases the risk of ovarian cancer in all users of these products.

All of my opinions in this report are provided with respect to a reasonable degree of medical and scientific certainty. I reserve the right to amend or supplement my report as new information becomes available.

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Exhibit A

Curriculum Vitae

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Biosketch

Arch "Chip" Carson, MD, PhD is a physician (The Ohio State University), board certified in Occupational Medicine (American Board of Preventive Medicine), who holds a Doctor of Philosophy degree in Toxicology (University of Cincinnati, Kettering Laboratory). He has served on the faculty of the University of Cincinnati and the New York University Medical Center and joined the faculty of the University of Texas School of Public Health in 1992 in its Environmental Sciences Discipline and Occupational and Environmental Health and Aerospace Medicine Module. He is Associate Professor of Occupational Health, directs the Occupational and Environmental Medicine Residency Program and is a member of the research team of the Southwest Center for Occupational and Environmental Health, a NIOSH Education and Research Center, and WHO Collaborating Centre in Occupational Health. He maintains a clinical practice of occupational medicine and medical toxicology. In his more recent role as Medical Director for the University of Texas Medical Branch in Galveston, he is responsible for the health monitoring and care of more than 15,000 employees. He is a frequent consultant to governments, corporations and the legal community on matters related to industrial chemical exposure, toxicology and environmental justice. His research interests include: environmental and occupational chemical exposures, inhalation injuries, metal exposures and cancer, and professional training in occupational medicine.

Professional Activities/Employment

2017-18	University of Texas Medical Branch, Galveston, Assistant Clinical Professor of Preventive Medicine and Family Medicine
2017-18	University of Texas Medical Branch, Galveston, Medical Director, Employee Health Services.
2017-18	Enbridge Corporation, Houston Texas, Medical Director, Employee Health Services.
2010-18	University of Texas Health Science Center, Houston, Associate Professor of Occupational Health.
2010-18	University of Texas Health Science Center at Houston, Program Director, Occupational and Environmental Medicine Residency.
1991-18	Private practice of Occupational Medicine and Toxicology, New York, Texas and Ohio.
2011-18	Spectra Energy Corporation, Houston Texas, Medical Director, Employee Health Services.
1997-13	Texas Medical Center Inc., Houston Texas, Medical Director, Employee Health Services.
1992-08	University of Texas School of Public Health, Assistant Professor of Occupational Medicine and Environmental Sciences.
1998-08	University of Texas Health Science Center at Houston, Program Director, Occupational and Environmental Medicine Residency.
2003-08	Southwest Center for Occupational and Environmental Health, Principal Investigator and Director, Diller Phosgene Exposure Incident Registry of the American Chemistry Council.

2000-06	Chevron Phillips Chemical Company, Houston Texas, Corporate Medical Director.
2003-05	U.S. Department of Energy Office of Worker Advocacy Physician Review Panel Appointee.
1997-04	Southwest Center for Occupational and Environmental Health, Principal Investigator, City of Houston Lead Poisoning Epidemiology Project.
1992-03	UT Health Services, University of Texas Houston Health Science Center, Attending Physician, Occupational Medicine and Toxicology.
1997-01	University of Houston Downtown, Medical Director, Student Health Service.
1998-99	University of Texas School of Public Health, Convener of the Occupational/Environmental Health and Aerospace Medicine Module.
1992-97	Respiratory Consultants of Houston, PA, Attending Physician, Occupational Medicine and Toxicology.
1992-95	Exxon Chemical Americas, Baytown Polymer Center and Basic Chemicals Technology, Baytown TX, Consultant Physician.
1990-91	New York University Medical Center, Bellevue Hospital, Tisch Hospital, and Manhattan VA Hospital, New York NY, Dept. of Medicine, Clinical Instructor.
1982-90	Chemical Information Services Inc, Cincinnati OH, Associate in Toxicology.
1978-87	University of Cincinnati College of Medicine, Cincinnati OH, Instructor and Lecturer, Adjunct Assistant Professor of Industrial Toxicology.
1974-79	University of Cincinnati College of Medicine, Kettering Laboratory, Cincinnati OH, Research Technologist in Occupational Medicine and Clinical Studies.
1969-74	Millstone Inc., Cincinnati OH, Design Engineer, environmental control systems.

Educational Background

2002	Certificate of Board Eligibility, Medical Toxicology, American Board of Preventive Medicine/American Board of Emergency Medicine
1992	Certificate of Training - Residency in Occupational Medicine University of Texas Health Science Center at Houston, School of Public Health, and Southwest Center for Occupational and Environmental Health, Houston TX, 1992.
1991	Certificate of Training - Postgraduate Internship in Internal Medicine, New York University Medical Center and Bellevue Hospital Center, New York NY.
1990	MD - Ohio State University College of Medicine, Columbus OH.
1987	PhD - Kettering Laboratory, University of Cincinnati College of Medicine, Cincinnati OH, awarded in the field of "Environmental Health – Toxicology."
1973	BS - University of Cincinnati College of Arts and Sciences Cincinnati OH. Awarded in "Biological Sciences with Concentration in Engineering."
1969	Rensselaer Polytechnic Institute, Troy NY. Management Engineering
1968	Villa Madonna College, Covington KY. Certificate in Contemporary Physics.

Fellowships

2011-13	UTHealth, Health Educators Fellowship, University of Texas Health Science Center at Houston.
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- 1983-85 American Lung Association Fellowship in Lung Research (Inhalation Toxicology), American Lung Association of Southwestern Ohio, Grant.
- 1981-82 Owens Corning Fiberglas, Graduate Research Fellowship in Combustion Toxicology.
- 1979-80 National Institute for Occupational Safety and Health, Centers for Disease Control, Doctoral Fellowship in Industrial Toxicology.

Certifications

- 2012 License to practice medicine, State of Ohio 35.098635
- 2010 Certified Healthy Homes Specialist – National Environmental Health Association.
- 2002 Board Eligibility, Medical Toxicology, American Board of Preventive Medicine/American Board of Emergency Medicine.
- 1994 Board Certification, Occupational Medicine, American Board of Preventive Medicine.
- 1992 License to practice medicine, State of Texas J2524.
- 1991 License to practice medicine, State of New York 186563.
- 1982 Emergency Hazard Response, Environmental and Industrial Chemical Accident Management, U.S. Environmental Protection Agency.
- 1979 Pulmonary Function Testing for Occupational Surveillance, NIOSH #003.

Professional Community Service

- 2013-18 University of Texas Health Science Center at Houston, Steering Committee on Interprofessional Collaboration
- 2013-18 University of Texas Health Science Center at Houston, Chemical Safety Committee.
- 1998-18 Association of Environmental and Occupational Clinics/ATSDR community resource on toxic exposures and health consequences, Federal Region VI.
- 1997-18 City of Houston Biological, Chemical and Radiation Emergency Preparedness Program. Medical Toxicology On-Call Advisor to the Houston Medical Strike Team.
- 1998-18 Association of Occupational and Environmental Medicine Residency Directors. Chairman 2005-2006
- 2010-18 University of Texas Health Science Center at Houston, Graduate Medical
1997-08 Education Committee
- 2010-18 University of Texas Health Science Center, Houston, Community/Press
1994-08 Resource and Speaker via Public Information Office, (Toxic Exposures and Environmental Health).
- 1996-18 American College of Occupational and Environmental Medicine, Council on Academic Affairs and Co-chair, Academic Section 2004-2006. Occupational Medicine Residency Directors Committee, Chair 2006-2007, Appointed Member, Taskforce on the Future of Occupational Medicine Education 2005-2007. Appointed Co-chair, Taskforce on the Future of Occupational Medicine Education 2013-2015.
- 1996-18 Texas College of Occupational and Environmental Medicine. Secretary/Treasurer-2004-5, President Elect-2005-6, President-2006-7, Past President 2007-8.
- 2003-12 Boy Scouts of America, Sam Houston Council, Registered Adult Leader and Merit Badge Counselor.
- 2005-08 University of Texas School of Public Health, Practice Council Co-chair

2003-05	U.S. Department of Energy Office of Worker Advocacy Physician Review Panel Appointee.
1996-00	American Public Health Association, Occupational Health Subcommittee
1994-96	Advisory Board, National Environmental Education and Training Center (NEETC), Curriculum Development Committee.
1981-85	Tri-State Air Committee Inc., Cincinnati OH, (voluntary air quality organization) Scientific Advisor, Elected to Board of Directors in 1982, President and Chairman 1984-85.
1981-85	American Lung Association of Southwestern Ohio, Cincinnati OH, (voluntary health organization) speakers bureau.
1982-83	City of Cincinnati, Appointment to Occupational Health Scientific Liaison Board (municipal advisory committee).
1981-83	Cincinnati Area Toxic Substances Coalition, Cincinnati OH, (coalition of business, voluntary, and labor organizations with interest in environmental toxic substance issues) Cofounder and Chairman.
1982-83	Ohio River Valley Committee on Occupational Safety and Health, Cincinnati OH, (organized labor coalition) Scientific Resource Committee.
1972-82	Walnut Hills-Evanston Medical Center, Cincinnati OH, (primary care center) Board of Directors.

Professional Societies

1991-18	American College of Occupational and Environmental Medicine.
1991-18	Texas College of Occupational and Environmental Medicine
2007-18	Texas Public Health Association.
2006-18	International Congress on Occupational Health.
2003-18	American College of Medical Toxicology.
2002-06	Society of Occupational and Environmental Health.
2001-06	American Conference of Governmental Industrial Hygienists.
1994-00	American Public Health Association.
1983-87	American Industrial Hygiene Association.
1983-87	Society of Toxicology.
1980-85	American Thoracic Society, Associate Member and Participant in Occupational and Environment Scientific Session.

Publications

Anderson F, **Carson A**, Whitehead L and Burau K Age, Race and Gender Spatiotemporal Disparities of COPD Emergency Room Visits in Houston, Texas. Occupational Diseases and Environmental Medicine. 3:1-9, 2015. <http://dx.doi.org/10.4236/odem.2015.31001>.

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Calcote, JC, **Carson, A**, Peskin, MF, Emery, RJ. An assessment of post-disaster psychological stress in hazardous waste operations and emergency response (HAZWOPER) workers. *Disaster Med Public Health Preparedness*. 7:452-460, 2013. PMID 24274124.

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Bright K, Delclos G, **Carson A**, Felknor S, Mackey T, Morandi M, Schultz L and Whitehead L. A Global Study of Occupational Health Competencies and Curricula, Report to the World Health Organization, March, 2000, Southwest Center for Occupational and Environmental Health.

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Carson A, Hangoc V and Bahrainwala M, City of Houston Childhood Lead Poisoning Prevention Program: Case Density and Impact Analysis, June 30, 1999, Technical Report (Principal Investigator).

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Exhibit B

LITERATURE:

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- American Cancer Society. “Key Statistics for Ovarian Cancer.”
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- Anderson, Garnet L., Howard L. Judd, Andrew M. Kaunitz, David H. Barad, Shirley A. A. Beresford, Mary Pettinger, James Liu, S. Gene McNeeley, Ana Maria Lopez, and Women’s Health Initiative Investigators. “Effects of Estrogen plus Progestin on Gynecologic Cancers and Associated Diagnostic Procedures: The Women’s Health Initiative Randomized Trial.” *JAMA* 290, no. 13 (October 1, 2003): 1739–48.
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- Podzielinski, Christopher P. DeSimone, Fred R. Ueland, John R. van Nagell, and Leigh G. Seamon. "Ten-Year Relative Survival for Epithelial Ovarian Cancer." *Obstetrics & Gynecology* 120, no. 3 (September 2012): 612–18.
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- Belotte, Jimmy, Nicole M. Fletcher, Mohammed G. Saed, Mohammed S. Abusamaan, Gregory Dyson, Michael P. Diamond, and Ghassan M. Saed. "A Single Nucleotide Polymorphism in Catalase Is Strongly Associated with Ovarian Cancer Survival." *PloS One* 10, no. 8 (2015).
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- F344/N Rats and B6C3F1 Mice.” *Regulatory Toxicology and Pharmacology: RTP* 21, no. 2 (April 1995): 242–43.
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DEPOSITIONS, TRANSCRIPTS AND REPORTS:

Affidavit of Laura Plunkett, PhD 02.22.18

Deposition of Alice Blount in the Ingham v. J&J Matter on 04.13.18

Deposition of Annie Awanaiss Yessian on 07.13.2017

Deposition and Exhibits of Pat Downey Dated 8.7.18-8.8.18
Deposition and Exhibits of John Hopkins Dated 8.16.18-8.17.18, 10.17.18 and 11.05.18
Deposition and Exhibits of Susan Nicholson Dated 7.26.18-7.27.18
Deposition and Exhibits of Julie Pier Dated 9.12.18-9.13.18
Ingham v. J&J Volume 11 (Egilman, Koman, Martinez, Packard) 6-14-18
Ingham v. J&J Volume 14A (Madigan, Williams) 6-20-18
Ingham v. JJ Volume 24A (Warner Huh, MD) 7.5.18
Ingham v. JJ Volume 24B (Warner Huh, MD) 7.5.18
John J. Godleski Expert Report for Brower Matter Dated 6.23.18
Lanzo Plaintiffs MIL re Imerys Spoliation and Concealment of Talc Samples
Laura Plunkett - Supplemental Expert Brower Report
Longo Analysis of J&J's Historical Talc Samples from the 1960's
Longo Analysis of J&J's Historical Talc Samples from the 1970's
Longo Analysis of J&J's Historical Talc Samples from the 1980's
Longo Analysis of J&J's Historical Talc Samples from the 1990's
Longo Analysis of J&J's Baby Powder Historical Samples - Asian - October 2018
Longo Analysis of J&J's BP Talc Products for Amphibole (Tremolite) Asbestos 8.2.17
Longo Analysis Report_Exhibit BB_04.28.2017
Longo MAS Project 14-1852 Below the Waist Application of Johnson's BP 9.2017
Longo Process Blanks for the Analysis of J&J's Products from the 60's to 90's for Asbestos
Longo TEM Analysis of Historical 1978 Johnson's BP Sample for Amphibole Asbestos 2.16.18
Longo Verification of Lee Poye's TEM Analysis of J&J's Historical Vermont Talc 11.5.18
Michael Crowley Expert Report Dated 11.12.18
Report of Results: MVA11730 Investigation of Italian Talc Samples for Asbestos 08.01.2017
RJLEE-001497
Thomas Dydek Brower Expert Report Dated 8.16.18 (corrected on 8.20.18)
Thomas Dydek Educational Report_FINAL (4-9-2018)
Thomas Dydek MDL Educational Report Dated 4.9.18

OTHER SOURCES:

American Cancer Society Ovarian Cancer Statistics
ATSDR Toxicological Profile for Asbestos
EPA Chemical Assessment Summary for Asbestos - 2017
EPA Guidelines for Carcinogen Risk Assessment - March 2005
EPA Health Assessment Document for Talc - 1992
Exhibit 1 - ATTORNEYS' EYES ONLY
Exhibit 2 - ATTORNEYS' EYES ONLY
Exhibit 3 - ATTORNEYS' EYES ONLY
FDA 4-1-2014 Response Letter to Epstein Denying Petition
Fitzgerald Analysis of J&J Baby Powder #1 and #2 Dated July 26, 2017
IARC Monograph 100C - Arsenic, Metals, Fibres, and Dusts - Excerpts
IARC Monograph 14 - Asbestos - 1977

IARC Monograph 2 - Some Inorganic and Organometallic Compounds - 1973
IARC Monograph 68 - Silica, Some Silicates, Coal Dust and Para-Aramid Fibrils - 1997
IARC Monograph 74 - Surgical Implants and Other Foreign Bodies - 1999
IARC Monograph 82 - Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene - 2002
IARC Monograph 86 - Cobalt in Hard Minerals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide - 2006
IARC Monograph 87 - Inorganic and Organic Lead Compounds – 2006

IMERYS013188	J&J History
IMERYS045182	J&J S2s and BP Product Analysis - 1972
IMERYS045184	JNJ 000087928
IMERYS048311	JNJ 000088570
IMERYS051370	JNJ 000285351
IMERYS053387	JNJ000025132
IMERYS090653	JNJ000062359
IMERYS098115	JNJ000062436
IMERYS105215	JNJ000063608
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IMERYS210729	JNJ000064544
IMERYS219720	JNJ000064762; JNJ000265171
IMERYS286445	JNJ000065264
IMERYS304036	JNJ000065601
IMERYS340454	JNJ000087710
IMERYS340798	JNJ000087716
IMERYS342524	JNJ000089413
IMERYS406170	JNJ000231304
IMERYS422289	JNJ000237076
IMERYS 088907	JNJ000237379
IMERYS 284935	JNJ000239723
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IMERYS209971	JNJ000245002
IMERYS241866	JNJ000246437
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IMERYS281335	JNJ000347962
IMERYS281776	JNJ000521616
IMERYS324700	JNJ000000704
IMERYS-A_0011817	JNJ000011150
IMERYS-A_0015663	JNJ000016645

JNJ000019415

JNJ000025132

JNJ000026987

JNJ000046293

JNJ000245678

JNJ000245762

JNJ000251888

JNJ000260700

JNJ000261010

JNJ000265536

JNJ000279507

JNJ000348778

JNJ000404860

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Pltf_MISC_00000272 (JANSSEN-000001-19)

NIOSH Occupation Respiratory Diseases September 1986

NIOSH Preliminary Report on Fiber Exposure During Use of Baby Powders - 1972

NTP Technical Report on the Toxicology and Carcinogenesis Studies of Talc (CAS No.
14807-96-6)- 1993

NTP Toxicology and Carcinogenesis Studies of Talc in F344/N Rats and B6C3F Mice Report
No. 421

P-468

Read-the-Letter-from-the-FDA-on-Cosmetics

The Birth of Our Baby Products _ Kilmer House

WCD 002478 - Exhibit 32 Waldstreicher

JNJ000460665

JNJ000526750

JNJ000886067

JNJAZ55_000000577

JNJAZ55_000000905

JNJAZ55_000004563

JNJAZ55_000008177

JNJL61_000014431

JNJMX68_000003728

JNJMX68_000012858

JNJMX68_000013019

JNJNL61_000079334

Arch Carson, MD, PhD Legal Testimony, 2015-2018

Elaine Hale and Kenneth Dorsey parker, Jr. v. Centerpoint Energy Houston Electric, LLC; in the 55th
District Court of Harris County, Texas.

2016 Harris County, TX for Plaintiff

Danny Henderson and Linda Henderson; Magdaleno Flores and Maria Flores; Shari Waldrop; and Bryan
Thomas v. Magnablend, Inc., Nugreen Specialty, Inc., Nugreen Solutions, Inc., and Enviro Tech Inc.; in
the 40th District Court of Ellis County, Texas.

2015 Ellis County, TX for Defendant

Edgar Guadalupe Solis v. Eastman Chemical Company, Texas Operations, Tradebe Environmental
Services, Inc. d/b/a Tradebe Industrial Services LLC; in the 234th District Court of Harris County, Texas.

2015 Harris County, TX for Defendant

Arch I. Carson, MD, PhD
Professional Consultation Fee Schedule

Evidence-base research, report preparation, documentation, conference	\$450/hr
Interview, physical examination or medical testing of patients	450/hr
Review of documents	450/hr
Testimony at deposition or trial plus expenses	450/hr
Inspection, examination or sampling of physical evidence or sites	450/hr
Travel (Travel maximum \$4,000 per diem, plus expenses)	200/hr
Laboratory analyses/studies	at cost
Overhead and Supplies	at cost